To: Younes, Lina[Younes.Lina@epa.gov]
Cc: Martinez, Brittany[Martinez.Brittany@epa.gov]
From: Larimer, Lisa
Sent: Tue 11/22/2016 9:40:51 PM
Subject: RE: Translation forms & documents for EPA-FDA fish advice

Ex. 5 - Deliberative Process was included with the Spanish request. The email you sent said you were approving the Spanish but wanted more information on Ex. 5 - Deliberative Process which we discussed.

From: Younes, Lina
Sent: Tuesday, November 22, 2016 2:42 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Martinez, Brittany <Martinez.Brittany@epa.gov>
Subject: Re: Translation forms & documents for EPA-FDA fish advice

I'm not sure I saw the first form. But I'll approve it.

Lina Younes

Multilingual Communications Liaison

EPA Office of Web Communications

202-564-9924

younes.lina@epa.gov

Facebook.com/epaespanol

Twitter.com/epaespanol

On Nov 22, 2016, at 2:24 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

> I've submitted another form for the additional languages we discussed, so you should be receiving that soon. **Ex. 5 - Deliberative Process**
>
> -Lisa

From: Younes, Lina
Sent: Friday, November 18, 2016 4:14 PM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>; Language Services Contracts Request <Language_Services_Contracts_Request@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
Subject: Re: Translation forms & documents for EPA-FDA fish advice

I've approved the translation of this document into Spanish, but would like further clarification of the choice of Ex. 5 - Deliberative Process May consider approving for Ex. 5 - Deliberative Process too, but consider that translation into Ex. 5 - Deliberative Process may be a better choice.

See attached.

Ex. 5 - Deliberative Process

Lina Younes
Multilingual Communications Liaison
Office of Web Communications
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW, RM 2513-K

William Jefferson Clinton North --Mail Code: 1703A
Washington, DC 20460
202-564-9924-office

202-494-4419-cell

younes.lina@epa.gov

Visit EPA's Spanish website: espanol.epa.gov
Facebook.com/epaespanol
Twitter.com/epaespanol

From: Altieri, Sonia
Sent: Friday, November 18, 2016 3:58:38 PM
To: Language Services Contracts Request
Cc: Larimer, Lisa; Lalley, Cara; Christensen, Christina; Loop, Travis; Younes, Lina
Subject: Translation forms & documents for EPA-FDA fish advice

Attached are the translation requests for the EPA-FED fish consumption advice. Based on previous conversations, this request meets the criteria of the LEP Executive Order. Please let me know if this is the case and if you have any questions. Thanks so much! Sonia

From: Larimer, Lisa
Sent: Friday, November 18, 2016 11:53 AM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
Subject: Translation forms & documents for EPA-FDA fish advice

Hi Sonia,

Cara Lalley is out of the office today, so I'm sending these to you directly. Attached are the forms requesting translation of two documents into Ex. 5 - Deliberative Process and the documents themselves: text for a chart and Q&A. Please let me know if you need anything else. I am teleworking today at Ex. 6 - Personal Privacy

---

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Younes, Lina[Younes.Lina@epa.gov]
From: Larimer, Lisa
Sent: Tue 11/22/2016 7:24:15 PM
Subject: RE: Translation forms & documents for EPA-FDA fish advice

I've submitted another form for the additional languages we discussed, so you should be receiving that soon. **Ex. 5 - Deliberative Process**

-Lisa

From: Younes, Lina
Sent: Friday, November 18, 2016 4:14 PM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>; Language Services Contracts Request <Language_Services_Contracts_Request@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
Subject: Re: Translation forms & documents for EPA-FDA fish advice

Ex. 5 - Deliberative Process

See attached.

Ex. 5 - Deliberative Process

Lina Younes
Multilingual Communications Liaison
Office of Web Communications

U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW, RM 2513-K

William Jefferson Clinton North --Mail Code: 1703A
Washington, DC 20460
202-564-9924-office

202-494-4419-cell

younes.lina@epa.gov

Visit EPA's Spanish website: espanol.epa.gov
Facebook.com/epaespanol
Twitter.com/epaespanol

From: Altieri, Sonia
Sent: Friday, November 18, 2016 3:58:38 PM
To: Language Services Contracts Request
Cc: Larimer, Lisa; Lalley, Cara; Christensen, Christina; Loop, Travis; Younes, Lina
Subject: Translation forms & documents for EPA-FDA fish advice

Attached are the translation requests for the EPA-FED fish consumption advice. Based on previous conversations, this request meets the criteria of the LEP Executive Order. Please let me know if this is the case and if you have any questions. Thanks so much! Sonia

From: Larimer, Lisa
Sent: Friday, November 18, 2016 11:53 AM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
Subject: Translation forms & documents for EPA-FDA fish advice

Hi Sonia,

Cara Lalley is out of the office today, so I'm sending these to you directly. Attached are the forms requesting translation of two documents into Ex. 5 - Deliberative Process, and the documents

themselves: text for a chart and Q&A. Please let me know if you need anything else. I am teleworking today at Ex. 6 - Personal Privacy

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Altieri, Sonia[Altieri.Sonia@epa.gov]
Cc: Lalley, Cara[Lalley.Cara@epa.gov]; Christensen, Christina[Christensen.Christina@epa.gov]
Bcc: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Tue 11/22/2016 6:56:26 PM
Subject: Second set of translation forms & documents for EPA-FDA fish advice
Text version of fish advice chart for translation.docx
Fish Advice Qs and As -for translation.docx
Translation Request Form2-fish advice Q and A.pdf
Translation Request Form2-fish advice chart.pdf

Sonia,

Here are the forms requesting translations in the other languages.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Barash, Shari[Barash.Shari@epa.gov]; Vlcan, Manjali[Vlcan.Manjali@epa.gov]
From: Larimer, Lisa
Sent: Thur 7/21/2016 12:56:00 PM
Subject: Re: Do you have items for NB general tomorrow?

GAO call is all I can think of, other than the fish advice peer review plan was posted this week.

From: Barash, Shari
Sent: Thursday, July 21, 2016 8:21:14 AM
To: Larimer, Lisa; Vlcan, Manjali
Subject: RE: Do you have items for NB general tomorrow?

Updating to:
- WY 60 day duration on secondary contact
- a attendance at climate FAQ meeting
- IL Rec Use
- call with R10 RTOC
- call with GAO on Beach Program
- Personnel

Lisa, let me know by 12 noon if you have anything else.

Shari Z. Barash
Chief
National Branch
Office of Water
US EPA
Washington, DC
202-566-0996
barash.shari@epa.gov

-----Original Message-----
From: Barash, Shari
Sent: Wednesday, July 20, 2016 5:20 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Vlcan, Manjali <Vlcan.Manjali@epa.gov>
Subject: Do you have items for NB general tomorrow?

I have some personnel things and:
- WY 60 day duration on secondary contact
- a attendance at climate FAQ meeting
- call with R10 RTOC
Did we want to make her aware of IL Rec use issue or have RB do it?

Sent from my iPhone

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Tue 11/22/2016 6:28:31 PM
Subject: Looking for your feedback: additional translations for fish advice

Shari,

I talked with Lina Younes yesterday and bottom line is she recommends getting additional translations done ASAP. We can discuss by phone if you like.

I would like to get both the chart and Q&A translated into Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Any concerns?

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Mon 11/21/2016 5:03:29 PM
Subject: when did work on this version of fish advice start - 2010?

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Mon 11/21/2016 3:56:31 PM
Subject: RE: draft tweets for fish advice guidance

Nah. I just threw some placeholders in.

From: Christensen, Christina
Sent: Monday, November 21, 2016 10:38 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: draft tweets for fish advice guidance

Did you draft some?? I must have missed that. I'm sure they are even better ☺

From: Larimer, Lisa
Sent: Monday, November 21, 2016 10:36 AM
To: Christensen, Christina <Christensen.Christina@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>
Subject: RE: draft tweets for fish advice guidance

Didn't like mine, eh? ☺

From: Christensen, Christina
Sent: Monday, November 21, 2016 10:27 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: draft tweets for fish advice guidance

Here are some ideas, just to get the ball rolling. I didn't include character counts since I don't have the web link, but all are less than 140 characters with room to spare for the link.

Ex. 5 - Deliberative Process

To: Younes, Lina[Younes.Lina@epa.gov]; Altieri, Sonia[Altieri.Sonia@epa.gov]; Language Services Contracts Request[Language_Services_Contracts_Request@epa.gov]
Cc: Lalley, Cara[Lalley.Cara@epa.gov]; Christensen, Christina[Christensen.Christina@epa.gov]; Loop, Travis[Loop.Travis@epa.gov]
From: Larimer, Lisa
Sent: Fri 11/18/2016 9:25:57 PM
Subject: RE: Translation forms & documents for EPA-FDA fish advice

Hi Lina. I understand your concern and welcome the opportunity to explain why we are requesting Spanish and Ex. 5 - Deliberative Process now. We are trying to get phase 1 of our translations done now for a December 9th release. Phase 2 will definitely include **Ex. 5 - Deliberative Process** We are also considering **Ex. 5 - Deliberative Process** We were thinking that by including **Ex. 5 - Deliberative Process** **Ex. 5 - Deliberative Process** The reason why ONLY Spanish and Ex. 5 - Deliberative Process at this time is because this is a joint project with FDA, and those two languages are they only ones they will commit to with their current graphic designer to make the fish advice charts. To do the chart in other languages (I'm assuming because of the different alphabets), they need to get to other contractors and it won't be timely enough for the 12/9 release.

I would appreciate your thoughts on the languages we are considering for Phase 2 and if Ex. 5 - Deliberative Process really doesn't make sense.

Thanks,

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Younes, Lina
Sent: Friday, November 18, 2016 4:03 PM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>; Language Services Contracts Request

<Language_Services_Contracts_Request@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
Subject: Re: Translation forms & documents for EPA-FDA fish advice

While I'm definitely supportive of the translation request, I have some questions regarding the language choice.

Ex. 5 - Deliberative Process

Why not **Ex. 5 - Deliberative Process** ?

Lina Younes
Multilingual Communications Liaison
Office of Web Communications
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW, RM 2513-K

William Jefferson Clinton North --Mail Code: 1703A
Washington, DC 20460
202-564-9924-office

202-494-4419-cell

younes.lina@epa.gov

Visit EPA's Spanish website: espanol.epa.gov
Facebook.com/epaespanol
Twitter.com/epaespanol

From: Altieri, Sonia
Sent: Friday, November 18, 2016 3:58:38 PM
To: Language Services Contracts Request
Cc: Larimer, Lisa; Lalley, Cara; Christensen, Christina; Loop, Travis; Younes, Lina
Subject: Translation forms & documents for EPA-FDA fish advice

Attached are the translation requests for the EPA-FED fish consumption advice. Based on previous conversations, this request meets the criteria of the LEP Executive Order. Please let me know if this is the case and if you have any questions. Thanks so much! Sonia

From: Larimer, Lisa
Sent: Friday, November 18, 2016 11:53 AM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
Subject: Translation forms & documents for EPA-FDA fish advice

Hi Sonia,

Cara Lalley is out of the office today, so I'm sending these to you directly. Attached are the forms requesting translation of two documents into Ex. 5 - Deliberative Process and the documents themselves: text for a chart and Q&A. Please let me know if you need anything else. I am teleworking today at Ex. 6 - Personal Privacy

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Fri 11/18/2016 2:50:22 PM
Subject: RE: price and timing estimates for document translations

Awesome. Thanks.

-----Original Message-----
From: Christensen, Christina
Sent: Friday, November 18, 2016 9:34 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: price and timing estimates for document translations

I say in the interest of time, send directly to Sonia and cc: Cara and myself.

-----Original Message-----
From: Larimer, Lisa
Sent: Friday, November 18, 2016 9:33 AM
To: Christensen, Christina <Christensen.Christina@epa.gov>
Subject: RE: price and timing estimates for document translations

When I get them done, do you want me to send them to you, or directly to Sonia and cc you and Cara?

-----Original Message-----
From: Christensen, Christina
Sent: Friday, November 18, 2016 9:28 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Cc: Barash, Shari <Barash.Shari@epa.gov>
Subject: RE: price and timing estimates for document translations

Checked with Sonia - one form is fine for all language requests.

-----Original Message-----
From: Larimer, Lisa
Sent: Friday, November 18, 2016 9:14 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: RE: price and timing estimates for document translations

Clarification question, Cara: We're going to go forward with Ex. 5 - Deliberative Process for the rollout (those are the only ones FDA would commit to for the chart in such a short timeframe). Do I need to submit a separate form for the chart in Ex. 5 - Deliberative Process and another for the chart in Ex. 5 - Deliberative Process? (and of course additions forms for the Q&A) The form has a line asking which language(s) to be translated in, so to me this implies I could use one form for both languages.

Let me know if I need to fill out one form or two for each document.
Thanks,
Lisa

-----Original Message-----
From: Lalley, Cara
Sent: Wednesday, November 16, 2016 12:43 PM
To: Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>

Subject: FW: price and timing estimates for document translations

Please see the translation price estimates for each language below.

Attached is the form that we would need to fill out for each document in each language we request. E.g.,

Ex. 5 - Deliberative Process

I removed the watermark and attempted to save the PDF chart as a Word document, and fix the errors that show up due to formatting differences, but there were several errors that I could not fix in Word. On the request form, you can try to submit the PDF chart for translation to both a Word and PDF chart, but I don't know if the OCR contractors will be able to maintain the proper formatting in Word. If FDA really can't provide a Word version of the chart, I guess we'll have to cross fingers that we or FDA will be able to later utilize the translated PDF content to create other multilingual outreach materials (e.g., a multi-fold brochure that merges the chart with the key FAQs). Copying and pasting Word content just seems to be the easiest and most cost effective use of the translated content down the road. But maybe FDA's contractors disagree.

Let me know how you want to proceed so I can fill in Travis and Sonia.

Thanks

-----Original Message-----
From: Altieri, Sonia
Sent: Wednesday, November 16, 2016 12:12 PM
To: Martinez, Brittany <Martinez.Brittany@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Loop, Travis <Loop.Travis@epa.gov>; Younes, Lina <Younes.Lina@epa.gov>; Nieves-Munoz, Waleska <Nieves-Munoz.Waleska@epa.gov>
Subject: RE: price and timing estimates for document translations

Thanks, Brittany, for providing this information.

Cara, Attached is the translation request form. When you're ready, please submit this form and the MS Word documents to me. Please let us know if you have any other questions. Best, Sonia

-----Original Message-----
From: Martinez, Brittany
Sent: Tuesday, November 15, 2016 9:11 AM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Younes, Lina <Younes.Lina@epa.gov>; Nieves-Munoz, Waleska <Nieves-Munoz.Waleska@epa.gov>
Subject: RE: price and timing estimates for document translations

Good morning-

The cost is based on the language and the price per word. Please see the following pricing as follows:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

The time it takes for the translator to translate depends on the length of a document. We typically like to give the contractor two weeks to turn a document around, but they may be able to complete the work sooner.

Once the English documents are ready, please submit to Sonia, so she can submit to the language request inbox.

Let me know if you have further questions.

-----Original Message-----
From: Altieri, Sonia
Sent: Tuesday, November 15, 2016 8:22 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Younes, Lina <Younes.Lina@epa.gov>; Martinez, Brittany <Martinez.Brittany@epa.gov>; Nieves-Munoz, Waleska <Nieves-Munoz.Waleska@epa.gov>
Subject: Re: price and timing estimates for document translations

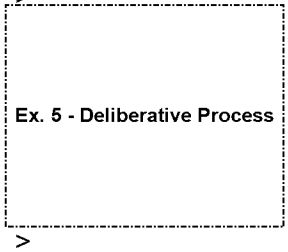
Brittany and Waleska,

See Cara's question about price and timing. This issue is sensitive. Don't distribute widely. Thanks!
Sonia

Sent from my iPhone

> On Nov 14, 2016, at 6:14 PM, Lalley, Cara <Lalley.Cara@epa.gov> wrote:
>
> Thanks, Lina. You are correct- once translated as Word documents (so we can copy and paste the language for later outreach purposes) these would eventually be converted to PDF for webposting. We would not try to post HTML advice in other languages. I only have the chart in PDF right now, but I'll ask the program staff if there is a Word/text version. If not, I have to assume we would only get the Spanish translation done for the mid-December release. Most of the other languages do not use our alphabet, so I don't know if we can copy and paste other alphabets to format charts in the other languages.
>
> Sonia, attached are final drafts of the two documents in question. Sorry, I didn't realize that the FAQs were actually about 3 pages in length; I was expecting 1 page. Thanks for your help getting estimates from OCR.
>
>
>
> From: Younes, Lina
> Sent: Monday, November 14, 2016 11:28 AM
> To: Lalley, Cara <Lalley.Cara@epa.gov>
> Cc: Altieri, Sonia <Altieri.Sonia@epa.gov>
> Subject: RE: price and timing estimates for document translations
>
> I'm happy to hear about this! Finally! I've been waiting for it for a while now!
>
> It sounds like a good plan. I'm cc'ing Sonia who can reach out to OCR for translation costs.
>
> Last I heard from OCR there is money available in the contract.
>
> And just a friendly reminder. When translating into languages other than Spanish, please let's translate PDFs only. Web pages in those other languages are nearly impossible to maintain given our lack of resources in those languages.

>
> Lina Younes
> Multilingual Communications Liaison
> Office of Web Communications
> EPA Office of Public Affairs
> US Environmental Protection Agency
> Washington, DC 20460
> 202-564-9924
> Visit EPA's Spanish portal at espanol.epa.gov Facebook.com/epaespanol
> Twitter.com/epaespanol Our Spanish blog:
> https://blog.epa.gov/blog/category/espanol/
>
> From: Lalley, Cara
> Sent: Monday, November 14, 2016 10:51 AM
> To: Younes, Lina <Younes.Lina@epa.gov<mailto:Younes.Lina@epa.gov>>
> Subject: price and timing estimates for document translations
>
> Hi Lina,
>
> Please don't share this widely, but I recently learned that FDA and EPA are hoping to release their final updated mercury fish consumption advice in mid-December. I sent a draft rollout to Travis Loop for review last week (and notified Sonia Altieri), and he will likely talk to OPA about it early this week. It includes questions about what outreach materials and what language translations are "must have" vs. "nice to have" and on what timeline. For example, if the advice goes out in mid-December, what if we can only have a 1-page graphical chart and 1 page of accompanying FAQs done by then (no tri-fold brochures, posters or other types of professional-looking outreach)? What if they can only be released initially in English and Spanish?
>
> Is there a flat rate for translation based on the length of a product, or does the price depend on the language, the technical complexity of the content? Would certain languages naturally take longer to translate than others? I should have a copy of both documents that I can share with you and Travis later today- but I'm guessing the key is that the chart includes many fish species names.
>
> We are still pulling together our full and final list, but here is a preliminary list of potential languages (some of which may not have to be finished by mid-December….I just don't know yet):
>
>



>
> Thanks,
>
> Cara Lalley
> Communications Coordinator
> Office of Science & Technology
> U.S. EPA Office of Water
> (202)566-0372 (p)
> (202)566-1140 (f)
>
> <EPA-FDA Final Fish Advice_Consumer FAQs -11 3 2016 clean.docx>
> <EPA-FDA final fish advice_consumer fish chart_draft 11-1-16.pdf>

To: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Fri 11/18/2016 2:32:57 PM
Subject: RE: price and timing estimates for document translations

When I get them done, do you want me to send them to you, or directly to Sonia and cc you and Cara?

-----Original Message-----
From: Christensen, Christina
Sent: Friday, November 18, 2016 9:28 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Cc: Barash, Shari <Barash.Shari@epa.gov>
Subject: RE: price and timing estimates for document translations

Checked with Sonia - one form is fine for all language requests.

-----Original Message-----
From: Larimer, Lisa
Sent: Friday, November 18, 2016 9:14 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: RE: price and timing estimates for document translations

Clarification question, Cara: We're going to go forward with Ex. 5 - Deliberative Process or the rollout (those are the only ones FDA would commit to for the chart in such a short timeframe). Do I need to submit a separate form for the chart in Ex. 6 - Personal Privacy and another for the chart in Ex. 6 - Personal Privacy? (and of course additions forms for the Q&A) The form has a line asking which language(s) to be translated in, so to me this implies I could use one form for both languages.

Let me know if I need to fill out one form or two for each document.
Thanks,
Lisa

-----Original Message-----
From: Lalley, Cara
Sent: Wednesday, November 16, 2016 12:43 PM
To: Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: FW: price and timing estimates for document translations

Please see the translation price estimates for each language below.

Attached is the form that we would need to fill out for each document in each language we request. E.g., a form for the Spanish chart and a form for the Spanish FAQ.

Ex. 5 - Deliberative Process

I removed the watermark and attempted to save the PDF chart as a Word document, and fix the errors that show up due to formatting differences, but there were several errors that I could not fix in Word. On the request form, you can try to submit the PDF chart for translation to both a Word and PDF chart, but I

don't know if the OCR contractors will be able to maintain the proper formatting in Word. If FDA really can't provide a Word version of the chart, I guess we'll have to cross fingers that we or FDA will be able to later utilize the translated PDF content to create other multilingual outreach materials (e.g., a multi-fold brochure that merges the chart with the key FAQs). Copying and pasting Word content just seems to be the easiest and most cost effective use of the translated content down the road. But maybe FDA's contractors disagree.

Let me know how you want to proceed so I can fill in Travis and Sonia.

Thanks

-----Original Message-----
From: Altieri, Sonia
Sent: Wednesday, November 16, 2016 12:12 PM
To: Martinez, Brittany <Martinez.Brittany@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Loop, Travis <Loop.Travis@epa.gov>; Younes, Lina <Younes.Lina@epa.gov>; Nieves-Munoz, Waleska <Nieves-Munoz.Waleska@epa.gov>
Subject: RE: price and timing estimates for document translations

Thanks, Brittany, for providing this information.

Cara, Attached is the translation request form. When you're ready, please submit this form and the MS Word documents to me. Please let us know if you have any other questions. Best, Sonia

-----Original Message-----
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Sent: Tuesday, November 15, 2016 9:11 AM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Younes, Lina <Younes.Lina@epa.gov>; Nieves-Munoz, Waleska <Nieves-Munoz.Waleska@epa.gov>
Subject: RE: price and timing estimates for document translations

Good morning-

The cost is based on the language and the price per word. Please see the following pricing as follows:

Ex. 5 - Deliberative Process

The time it takes for the translator to translate depends on the length of a document. We typically like to give the contractor two weeks to turn a document around, but they may be able to complete the work sooner.

Once the English documents are ready, please submit to Sonia, so she can submit to the language request inbox.

Let me know if you have further questions.

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<Martinez.Brittany@epa.gov>; Nieves-Munoz, Waleska <Nieves-Munoz.Waleska@epa.gov>
Subject: Re: price and timing estimates for document translations

Brittany and Waleska,

See Cara's question about price and timing. This issue is sensitive. Don't distribute widely. Thanks!
Sonia

Sent from my iPhone

> On Nov 14, 2016, at 6:14 PM, Lalley, Cara <Lalley.Cara@epa.gov> wrote:
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> Thanks, Lina. You are correct- once translated as Word documents (so we can copy and paste the language for later outreach purposes) these would eventually be converted to PDF for webposting. We would not try to post HTML advice in other languages. I only have the chart in PDF right now, but I'll ask the program staff if there is a Word/text version. If not, I have to assume we would only get the Spanish translation done for the mid-December release. Most of the other languages do not use our alphabet, so I don't know if we can copy and paste other alphabets to format charts in the other languages.
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> From: Younes, Lina
> Sent: Monday, November 14, 2016 11:28 AM
> To: Lalley, Cara <Lalley.Cara@epa.gov>
> Cc: Altieri, Sonia <Altieri.Sonia@epa.gov>
> Subject: RE: price and timing estimates for document translations
>
> I'm happy to hear about this! Finally! I've been waiting for it for a while now!
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> It sounds like a good plan. I'm cc'ing Sonia who can reach out to OCR for translation costs.
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> Last I heard from OCR there is money available in the contract.
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> And just a friendly reminder. When translating into languages other than Spanish, please let's translate PDFs only. Web pages in those other languages are nearly impossible to maintain given our lack of resources in those languages.
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> Lina Younes
> Multilingual Communications Liaison
> Office of Web Communications
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> Visit EPA's Spanish portal at espanol.epa.gov Facebook.com/epaespanol
> Twitter.com/epaespanol Our Spanish blog:
> https://blog.epa.gov/blog/category/espanol/
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> From: Lalley, Cara
> Sent: Monday, November 14, 2016 10:51 AM
> To: Younes, Lina <Younes.Lina@epa.gov<mailto:Younes.Lina@epa.gov>>
> Subject: price and timing estimates for document translations

>
> Hi Lina,
>
> Please don't share this widely, but I recently learned that FDA and EPA are hoping to release their final updated mercury fish consumption advice in mid-December. I sent a draft rollout to Travis Loop for review last week (and notified Sonia Altieri), and he will likely talk to OPA about it early this week. It includes questions about what outreach materials and what language translations are "must have" vs. "nice to have" and on what timeline. For example, if the advice goes out in mid-December, what if we can only have a 1-page graphical chart and 1 page of accompanying FAQs done by then (no tri-fold brochures, posters or other types of professional-looking outreach)? What if they can only be released initially in English and Spanish?
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> We are still pulling together our full and final list, but here is a preliminary list of potential languages (some of which may not have to be finished by mid-December….I just don't know yet):
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Ex. 5 - Deliberative Process

>
> Thanks,
>
> Cara Lalley
> Communications Coordinator
> Office of Science & Technology
> U.S. EPA Office of Water
> (202)566-0372 (p)
> (202)566-1140 (f)
>
> <EPA-FDA Final Fish Advice_Consumer FAQs -11 3 2016 clean.docx>
> <EPA-FDA final fish advice_consumer fish chart_draft 11-1-16.pdf>

To: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Fri 11/18/2016 2:32:21 PM
Subject: RE: price and timing estimates for document translations

Yay!

-----Original Message-----
From: Christensen, Christina
Sent: Friday, November 18, 2016 9:28 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Cc: Barash, Shari <Barash.Shari@epa.gov>
Subject: RE: price and timing estimates for document translations

Checked with Sonia - one form is fine for all language requests.

-----Original Message-----
From: Larimer, Lisa
Sent: Friday, November 18, 2016 9:14 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: RE: price and timing estimates for document translations

Clarification question, Cara: We're going to go forward with Ex. 5 - Deliberative Process for the rollout (those are the only ones FDA would commit to for the chart in such a short timeframe). Do I need to submit a separate form for the chart in Ex. 5 - Deliberative Process and another for the chart in Ex. 5 - Deliberative Process? (and of course additions forms for the Q&A) The form has a line asking which language(s) to be translated in, so to me this implies I could use one form for both languages.

Let me know if I need to fill out one form or two for each document.
Thanks,
Lisa

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Sent: Wednesday, November 16, 2016 12:43 PM
To: Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: FW: price and timing estimates for document translations

Please see the translation price estimates for each language below.

Attached is the form that we would need to fill out for each document in each language we request. E.g., a form for the Spanish chart and a form for the Spanish FAQ.

Ex. 5 - Deliberative Process

I removed the watermark and attempted to save the PDF chart as a Word document, and fix the errors that show up due to formatting differences, but there were several errors that I could not fix in Word. On the request form, you can try to submit the PDF chart for translation to both a Word and PDF chart, but I

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Ex. 5 - Deliberative Process

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> Cc: Altieri, Sonia <Altieri.Sonia@epa.gov>
> Subject: RE: price and timing estimates for document translations
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> It sounds like a good plan. I'm cc'ing Sonia who can reach out to OCR for translation costs.
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> Last I heard from OCR there is money available in the contract.
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> Lina Younes
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>
> <EPA-FDA Final Fish Advice_Consumer FAQs -11 3 2016 clean.docx>
> <EPA-FDA final fish advice_consumer fish chart_draft 11-1-16.pdf>

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Fri 11/18/2016 2:23:01 PM
Subject: RE: Does NOAA know we're coming out with new fish advice?

Can you call me about a few things when you get a few free minutes? I'm teleworking today and can be reached at Ex. 6 - Personal Privacy

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, November 14, 2016 1:57 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>
Cc: Wathen, John <Wathen.John@epa.gov>
Subject: RE: Does NOAA know we're coming out with new fish advice?

Good question. Ex. 5 - Deliberative Process Let's discuss by phone!

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Monday, November 14, 2016 1:42 PM
To: Natanblut, Sharon; Smegal, Deborah; Jones, William
Cc: Wathen, John
Subject: Does NOAA know we're coming out with new fish advice?

Since you all work with NOAA more than we do, I thought it might be likely. I thought we had good Q&A, but I've gotten questions if it might be confusing to consumers where NOAA says something is a good choice and we say avoid? See the following, cut from an email from one of our communications folks:

Does NOAA know that we are planning to put the final mercury advice out soon? Just wondering because of the interplay between their Fishwatch site and our FAQs, especially on sustainability. For example, we say to avoid bigeye tuna, but NOAA's site says it's a good choice: http://www.fishwatch.gov/profiles/atlantic-bigeye-tuna Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Fri 11/18/2016 2:17:02 PM
Subject: FW: price and timing estimates for document translations

Argh, Cara's out. Christina, if you're in the office today, can you check with Sonia Altieri?

-----Original Message-----
From: Larimer, Lisa
Sent: Friday, November 18, 2016 9:14 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: RE: price and timing estimates for document translations

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Thanks,
Lisa

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Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
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Ex. 5 - Deliberative Process

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> Visit EPA's Spanish portal at espanol.epa.gov Facebook.com/epaespanol
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> https://blog.epa.gov/blog/category/espanol/
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> <EPA-FDA final fish advice_consumer fish chart_draft 11-1-16.pdf>

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Fri 11/18/2016 1:44:00 PM
Subject: RE: Do you have a Word or text version of the fish advice chart to help with translations?

OK, I'll fill out the forms and get them to Cara.

From: Barash, Shari
Sent: Friday, November 18, 2016 8:20 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Do you have a Word or text version of the fish advice chart to help with translations?

I think that is what our comms people want – that is, as much outreach as possible with the roll out.

Shari Z. Barash

Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Larimer, Lisa
Sent: Thursday, November 17, 2016 10:48 PM
To: Barash, Shari <Barash.Shari@epa.gov>
Subject: FW: Do you have a Word or text version of the fish advice chart to help with translations?

So shall we plan on just moving Ex. 5 - Deliberative Process versions forward for release at or near the same time as the English version?

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, November 17, 2016 10:32 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Strachman-Miller, Jason <Jason.Strachman-Miller@fda.hhs.gov>
Subject: RE: Do you have a Word or text version of the fish advice chart to help with translations?

Lisa,

We can commit now to being able to get the Ex. 5 - Deliberative Process ones designed. For the others, we would need to work with a different designer.

Sharon

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, November 16, 2016 4:07 PM
To: Natanblut, Sharon
Cc: Strachman-Miller, Jason
Subject: RE: Do you have a Word or text version of the fish advice chart to help with translations?

I guess I should clarify, we are exploring getting the chart and Q&A translated into these languages ASAP: Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process Do you foresee any problems recreating the chart if translated into these languages?

From: Larimer, Lisa
Sent: Wednesday, November 16, 2016 3:55 PM
To: 'Natanblut, Sharon' <Sharon.Natanblut@fda.hhs.gov>
Cc: Strachman-Miller, Jason <Jason.Strachman-Miller@fda.hhs.gov>

Subject: RE: Do you have a Word or text version of the fish advice chart to help with translations?

Checking in before I send off for translations. If I get this text version translated (see attachment), you'll be able to recreate the chart, right?

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, November 15, 2016 4:22 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Strachman-Miller, Jason <Jason.Strachman-Miller@fda.hhs.gov>
Subject: Re: Do you have a Word or text version of the fish advice chart to help with translations?

Jason, do we have a word version of the seafood advice? Pls advise.

Yes, we would design them in other languages. Thanks!

Sent from my BlackBerry 10 smartphone.

From: Larimer, Lisa

Sent: Tuesday, November 15, 2016 4:19 PM

To: Natanblut, Sharon

Subject: Do you have a Word or text version of the fish advice chart to help with translations?

I'm guessing not, that it was produced in a graphics program. If that's the case, we'll deal. If I get the text translated, can I get you all to create charts in other languages?

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Fri 11/18/2016 3:47:44 AM
Subject: FW: Do you have a Word or text version of the fish advice chart to help with translations?

So shall we plan on just moving Ex. 5 - Deliberative Process versions forward for release at or near the same time as the English version?

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, November 17, 2016 10:32 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Strachman-Miller, Jason <Jason.Strachman-Miller@fda.hhs.gov>
Subject: RE: Do you have a Word or text version of the fish advice chart to help with translations?

Lisa,

We can commit now to being able to get the Ex. 5 - Deliberative Process ones designed. For the others, we would need to work with a different designer.

Sharon

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, November 16, 2016 4:07 PM
To: Natanblut, Sharon
Cc: Strachman-Miller, Jason
Subject: RE: Do you have a Word or text version of the fish advice chart to help with translations?

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Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process Do you foresee any problems recreating the chart if translated into these languages?

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Sent: Wednesday, November 16, 2016 3:55 PM
To: 'Natanblut, Sharon' <Sharon.Natanblut@fda.hhs.gov>
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202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
Cc: Strachman-Miller, Jason[Jason.Strachman-Miller@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 11/16/2016 9:06:50 PM
Subject: RE: Do you have a Word or text version of the fish advice chart to help with translations?

I guess I should clarify, we are exploring getting the chart and Q&A translated into these languages ASAP: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Do you foresee any problems recreating the chart if translated into these languages?

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Cc: Strachman-Miller, Jason <Jason.Strachman-Miller@fda.hhs.gov>
Subject: RE: Do you have a Word or text version of the fish advice chart to help with translations?

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Sent: Tuesday, November 15, 2016 4:22 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Strachman-Miller, Jason <Jason.Strachman-Miller@fda.hhs.gov>
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Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
Cc: Strachman-Miller, Jason[Jason.Strachman-Miller@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 11/16/2016 8:54:50 PM
Subject: RE: Do you have a Word or text version of the fish advice chart to help with translations?
Text version of chart for translation.docx

Checking in before I send off for translations. If I get this text version translated (see attachment), you'll be able to recreate the chart, right?

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, November 15, 2016 4:22 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Strachman-Miller, Jason <Jason.Strachman-Miller@fda.hhs.gov>
Subject: Re: Do you have a Word or text version of the fish advice chart to help with translations?

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Sent: Tuesday, November 15, 2016 4:19 PM

To: Natanblut, Sharon

Subject: Do you have a Word or text version of the fish advice chart to help with translations?

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Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Wed 11/16/2016 8:47:16 PM
Subject: Translation costs for fish advice

It will cost approximately Ex. 5 - Deliberative Process to translate the chart and Q&A into Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process We were thinking about translating into Ex. 5 - Deliberative Process too, but we'll have to request a quote for those; it appears the OCR contract doesn't have an agreed upon price for those.

Ex. 5 - Deliberative Process

Did you want to check in with Sara before moving forward?

Language	Used in 2004?	Cost per word	Chart-estimated cost	Q&A-estimated cost
Ex. 5 - Deliberative Process				
Total			**$**	**$** Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Word count - chart: 361
Word count - Q&A: 2652

To: Thalathara, Roselyn[thalathara.roselyn@epa.gov]
From: Larimer, Lisa
Sent: Wed 11/16/2016 6:54:37 PM
Subject: Quick request
FISH_CHART_H_11.3.pdf

Hi,

I realize this is a mundane request, but can you count how many words are on this chart? I need it to estimate translation costs. If you could do this before you leave today, that would be great.

Thanks!

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Tue 11/15/2016 9:19:26 PM
Subject: Do you have a Word or text version of the fish advice chart to help with translations?

I'm guessing not, that it was produced in a graphics program. If that's the case, we'll deal. If I get the text translated, can I get you all to create charts in other languages?

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Li, Cissy[Cissy.Li@fda.hhs.gov]
Cc: Dooren, Jennifer[Jennifer.Dooren@fda.hhs.gov]; Strachman-Miller, Jason[Jason.Strachman-Miller@fda.hhs.gov]; Li, Cissy[Cissy.Li@fda.hhs.gov]; Savidge, Matthew[Matthew.Savidge@fda.hhs.gov]
From: Larimer, Lisa
Sent: Mon 11/14/2016 9:52:59 PM
Subject: RE: updated fish advice comparison

Sorry, replied without scrolling down to get the context.

-----Original Message-----
From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, November 14, 2016 4:43 PM
To: Wathen, John <Wathen.John@epa.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Li, Cissy <Cissy.Li@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Strachman-Miller, Jason <Jason.Strachman-Miller@fda.hhs.gov>; Li, Cissy <Cissy.Li@fda.hhs.gov>; Savidge, Matthew <Matthew.Savidge@fda.hhs.gov>
Subject: RE: updated fish advice comparison

I totally am good with where FDA/EPA ended up -- I was just flagging that the chart needs to be corrected to reflect CR's position! Sorry for any confusion.

-----Original Message-----
From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Monday, November 14, 2016 4:41 PM
To: Natanblut, Sharon; Smegal, Deborah; Jones, William; Li, Cissy; Larimer, Lisa
Cc: Dooren, Jennifer; Strachman-Miller, Jason; Li, Cissy; Savidge, Matthew
Subject: RE: updated fish advice comparison

Sharon-

I read the CR report a while ago, and as I recall, they did fairly extensive sampling of purchased cans of tuna and based their reservation on the variability in mercury concentrations. This is not a trivial point that given the variability, the risk of consuming say 80th or 90th percentile tuna is real. We used the average mercury which is what your data and the others include. In buying food at the store, it can be argued that the averages work out both ways, unlike the sportfisher who catches a big old marlin and eats the whole fish over the winter.

~John

-----Original Message-----
From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, November 14, 2016 4:30 PM
To: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Li, Cissy <Cissy.Li@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Strachman-Miller, Jason <Jason.Strachman-Miller@fda.hhs.gov>; Li, Cissy <Cissy.Li@fda.hhs.gov>; Savidge, Matthew <Matthew.Savidge@fda.hhs.gov>
Subject: RE: updated fish advice comparison

I reviewed the Consumer Reports article and it says the following:

"Consumer Reports has said for some time that canned light tuna is not a good low-mercury choice and that pregnant women should not eat any tuna at all. Nothing in the new federal testing data or advice has given us cause to change that view, which also is shared by some scientists, such as Rice."

So shouldn't the chart show all types of tuna in the red category?
Thanks.
Sharon

-----Original Message-----
From: Smegal, Deborah
Sent: Monday, November 14, 2016 2:44 PM
To: Jones, William; Li, Cissy; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Cc: Dooren, Jennifer; Strachman-Miller, Jason; Li, Cissy; Savidge, Matthew
Subject: RE: updated fish advice comparison

Hi,

Here is an updated comparison table. Thanks to Cissy for developing this table.

Debbie

Deborah Smegal, MPH
Branch Chief, Contaminant Assessment Branch (CAB) Division of Risk and Decision Analysis Office of Analytics and Outreach CFSAN, FDA
240-402-1818

-----Original Message-----
From: Jones, William
Sent: Monday, November 07, 2016 1:52 PM
To: Smegal, Deborah; Li, Cissy; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Cc: Dooren, Jennifer; Strachman-Miller, Jason; Li, Cissy; Savidge, Matthew
Subject: RE: updated fish advice comparison

I like it, but I'm wondering if Ex. 5 - Deliberative Process

-----Original Message-----
From: Smegal, Deborah
Sent: Monday, November 07, 2016 10:36 AM
To: Li, Cissy; Natanblut, Sharon; Jones, William; Larimer, Lisa; Wathen, John
Cc: Dooren, Jennifer; Strachman-Miller, Jason; Li, Cissy; Savidge, Matthew
Subject: updated fish advice comparison

Hi,

Attached is an updated and QA'd version of the comparison between the FDA/EPA advice and others.
What do you think?
Thanks to Cissy and Matt for their work on this.

Regards,

Debbie

Deborah Smegal, MPH
Branch Chief, Contaminant Assessment Branch (CAB) Division of Risk and Decision Analysis Office of Analytics and Outreach CFSAN, FDA

240-402-1818

-----Original Message-----
From: Li, Cissy
Sent: Friday, November 04, 2016 3:23 PM
To: Natanblut, Sharon; Smegal, Deborah; Jones, William; Larimer, Lisa; Wathen, John
Cc: Dooren, Jennifer; Strachman-Miller, Jason
Subject: RE: Comparing other fish advice

Hi Sharon,

Thank you for catching that, you're right that Consumer Reports advises pregnant women to not eat any tuna. This recommendation was buried in the text of the article, while a series of charts showed fish consumption advice for the general population that allowed some tuna. You can see the article at this link: http://www.consumerreports.org/cro/magazine/2014/10/can-eating-the-wrong-fish-put-you-at-higher-risk-for-mercury-exposure/index.htm. The second page contains the general advice, and the third and fourth pages discuss tuna and pregnant women.

I will change my spreadsheet to better reflect pregnant women and children. This draft chart is also undergoing QA now.

Ex. 5 - Deliberative Process

Cissy

-----Original Message-----
From: Natanblut, Sharon
Sent: Friday, November 04, 2016 2:52 PM
To: Smegal, Deborah; Jones, William; Larimer, Lisa; Wathen, John
Cc: Li, Cissy; Dooren, Jennifer; Strachman-Miller, Jason
Subject: RE: Comparing other fish advice

This is great. I thought though that Consumer Reports and others put all tuna in the do not eat for pregnant women?

-----Original Message-----
From: Smegal, Deborah
Sent: Friday, November 04, 2016 2:35 PM
To: Jones, William; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Cc: Li, Cissy
Subject: FW: Comparing other fish advice

Hi,

Attached is a spreadsheet from Cissy that compares our FDA/EPA advice to other fish advice. I think this is excellent and shows **Ex. 5 - Deliberative Process**

Debbie

-----Original Message-----
From: Li, Cissy
Sent: Wednesday, November 02, 2016 2:07 PM
To: Smegal, Deborah
Subject: Comparing other fish advice

Hi Debbie,

Attached is a spreadsheet that compares the current FDA/EPA fish advice with 10 other fish advice from states and other groups. I did not search for each state's fish advice, I picked the ones that we were previously aware of from public comments or recent publications.

The first tab of the spreadsheet has more details, and the second tab is a visual summary of the information. The main conclusion is **Ex. 5 - Deliberative Process**

Let me know if you want any additional information to be included.

Cissy

Cissy Li, PhD
ORISE Fellow
Contaminant Assessment Branch
Division of Risk and Decision Analysis
Office of Analytics and Outreach, CFSAN, FDA Room 2A-031
240-402-2857

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Li, Cissy[Cissy.Li@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Dooren, Jennifer[Jennifer.Dooren@fda.hhs.gov]; Strachman-Miller, Jason[Jason.Strachman-Miller@fda.hhs.gov]; Li, Cissy[Cissy.Li@fda.hhs.gov]; Savidge, Matthew[Matthew.Savidge@fda.hhs.gov]
From: Larimer, Lisa
Sent: Mon 11/14/2016 9:39:30 PM
Subject: RE: updated fish advice comparison

The calculations based on the FDA dataset resulted in **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

-----Original Message-----
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Sent: Monday, November 14, 2016 4:30 PM
To: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Li, Cissy <Cissy.Li@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
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240-402-1818

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Ex. 5 - Deliberative Process

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Cissy

Cissy Li, PhD
ORISE Fellow
Contaminant Assessment Branch
Division of Risk and Decision Analysis
Office of Analytics and Outreach, CFSAN, FDA Room 2A-031
240-402-2857

To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]; Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]; Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Mon 11/14/2016 6:42:20 PM
Subject: Does NOAA know we're coming out with new fish advice?

Since you all work with NOAA more than we do, I thought it might be likely. I thought we had good Q&A, but I've gotten questions if it might be confusing to consumers where NOAA says something is a good choice and we say avoid? See the following, cut from an email from one of our communications folks:

Does NOAA know that we are planning to put the final mercury advice out soon? Just wondering because of the interplay between their Fishwatch site and our FAQs, especially on sustainability. For example, we say to avoid bigeye tuna, but NOAA's site says it's a good choice: http://www.fishwatch.gov/profiles/atlantic-bigeye-tuna **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]
Cc: Dooren, Jennifer[Jennifer.Dooren@fda.hhs.gov]
From: Larimer, Lisa
Sent: Mon 11/14/2016 4:55:58 PM
Subject: RE: EPA logo on fish advice chart

It sounds like the preference is to have our logo mirror yours, so since you changed from just FDA to the one that also spells out the agency name, please switch ours too, to the one I copied below. To get graphic quality versions, please contact the person below. If you have any problems, please let me know.

Thanks,

Lisa

From: Larimer, Lisa
Sent: Wednesday, November 02, 2016 4:53 PM
To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov) <Sharon.Natanblut@fda.hhs.gov>
Subject: EPA logo, rollout plan, press release, other languages for fish advice, and OMB help

Hi Sharon,

A couple quick things:

(1) I'm trying to get a definitive answer, but we may need to change the EPA logo on the chart to

It can be in white on a dark background, like we have it now. I don't have access to the print quality files, but I can put your designer In touch with the right person. It looks like it's Belinda Blackman (202-564-7844, blackman.belinda@epa.gov), based on this link: https://www.epa.gov/stylebook/using-epa-seal-and-logo#pro (which has info on the different

types of files available; I'm not sure what program your designer has been using to generate the charts).

(2) I'm getting crazy pressure for the rollout plan. I took the one we started working on jointly last year (at least I think it was jointly between the comms people) and started updating it. Before I get too far though, I wanted to check with you and make sure we're not concurrently duplicating efforts. So before I go any farther, here's what I've got (attached). Any chance you could look at it by Friday?

(3) Even if it's draft, can I get a version of the press release to plunk in the rollout plan? Thanks.

(4) My comms people are insisting we need to have this in other languages when we release in order to have a successful rollout. Since we have virtually no time, I'm pushing back that we can do other languages a little later. I'm probably going to lose on Spanish, though. Your thoughts on getting the press release, chart and Q&A into Spanish by 12/9?

(5) Given the short time OMB will have the materials, my managers are asking how we can help.

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Lalley, Cara[Lalley.Cara@epa.gov]
From: Larimer, Lisa
Sent: Tue 11/29/2016 7:07:00 PM
Subject: RE: Re:NOTE INSTRUCTIONS!!!!!!!! Second set of translation forms & documents for EPA-FDA fish advice

I think I did specify in the rollout, but perhaps not. And yes, let's get the web page changes lined up in advance. Remember, we've got direct link (epa.gov/fishadvice) that we can use directly or as a redirect to another page. At least I think we got approval for that link. Will have to dig through old email and check.

From: Lalley, Cara
Sent: Tuesday, November 29, 2016 2:01 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Subject: RE: Re:NOTE INSTRUCTIONS!!!!!!!! Second set of translation forms & documents for EPA-FDA fish advice

Much appreciated! I mean, Gracias- see, I know how to say that in Spanish!

I will still dig up the English version of the Spanish webpage tomorrow….we just need to tell Lina what is old and needs to be removed, and insert a new sentence that will lead people to the 2016 advice en español. Luckily, Spanish is her first language :) If I ever get the rollout back from Travis, we can clarify what languages are phase 1, 2, etc. and I can share it with Lina so she has an idea of the timeline for the web updates.

From: Larimer, Lisa
Sent: Tuesday, November 29, 2016 1:44 PM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Subject: RE: Re:NOTE INSTRUCTIONS!!!!!!!! Second set of translation forms & documents for EPA-FDA fish advice

OK, we've got different people on this email. To keep everyone in the loop, here is the revised Q&A file (thanks Cara!) and revised form with updated word count. I've sent them to Sonia so she can send them to OCR.

I'm keeping Spanish separate – it's on a different timeline than the others. I'm pretty sure we can figure out how and where to insert "(en ingles)" in the Q&A. ☺

From: Lalley, Cara
Sent: Tuesday, November 29, 2016 1:01 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Subject: FW: Re:NOTE INSTRUCTIONS!!!!!!!! Second set of translation forms & documents for EPA-FDA fish advice

Per Lina's message below, I attempted to add all the necessary "in English" phrases throughout the Q&A document. Can you look through the attachment and see if I missed any? We could move forward with updating the word count on the translation form for all the other languages, and deal with Spanish separately. Or, just lump Spanish in with the other languages and remember to remove the one "in English" parenthetical from the translated document once we update the Espanol webpage to reflect the 2016 advice.

See my comment in the attachment where it links to EPA's homepage on fish advisories. Either way, we need to figure out how to best update the Espanol webpage. When I'm back in the office tomorrow, I'll dig up the English version of that webpage. In case Sam is in the office today and has that, I'm copying her.

thanks

From: Lalley, Cara
Sent: Tuesday, November 29, 2016 12:11 PM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Re:NOTE INSTRUCTIONS!!!!!!!! Second set of translation forms & documents for EPA-FDA fish advice

So we need to revise the forms to reflect the addition of the HTML word count?

From: Altieri, Sonia
Sent: Tuesday, November 29, 2016 11:58 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>
Subject: RE: Re:NOTE INSTRUCTIONS!!!!!!!! Second set of translation forms & documents for EPA-FDA fish advice

Lisa and Cara,

I didn't see a response to Lina's email. I'm checking in with you.....Sonia

From: Younes, Lina
Sent: Wednesday, November 23, 2016 9:32 AM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>; Language Services Contracts Request <Language_Services_Contracts_Request@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
Subject: Re:NOTE INSTRUCTIONS!!!!!!!! Second set of translation forms & documents for EPA-FDA fish advice

Please note-that the second document, the Qs and As, includes several links. All of them link to English content. I think there might be one or two links that have related Spanish content.

Since we're translating these documents into multiple languages, we need to include in the hyperlinked text WHICH NEEDS TO be translated the following

(in English)

For example technical page (in English).

sortable table (in English)

2005 FDA survey (in English)

and the results are available in English on FDA's website:
http://www.fda.gov/food/foodborneillnesscontaminants/pesticides/ucm2006797.htm;
http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/ucm184293.htm.

Also see EPA's website for fish consumption advisories in English: http://www2.epa.gov/choose-fish-and-shellfish-wisely

You need to add in English appropriately before or after each hyperlink and ADD THAT TO THE WORD COUNT since those secondary pages lead to English content!!!!!

If you have any questions, please let me know.

Lina Younes
Multilingual Communications Liaison
Office of Web Communications
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW, RM 2513-K

William Jefferson Clinton North --Mail Code: 1703A
Washington, DC 20460
202-564-9924-office

202-494-4419-cell

younes.lina@epa.gov

Visit EPA's Spanish website: espanol.epa.gov
Facebook.com/epaespanol
Twitter.com/epaespanol

From: Altieri, Sonia
Sent: Tuesday, November 22, 2016 4:47 PM
To: Language Services Contracts Request; Younes, Lina
Cc: Larimer, Lisa; Lalley, Cara; Christensen, Christina; Loop, Travis
Subject: Second set of translation forms & documents for EPA-FDA fish advice

Attached are the additional translation requests for the EPA-FDA fish advice (Languages: **Ex. 5 - Deliberative Process**. This material is for U.S. communities.

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Sonia,

Here are the forms requesting translations in the other languages.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Lalley, Cara[Lalley.Cara@epa.gov]; Altieri, Sonia[Altieri.Sonia@epa.gov]
From: Larimer, Lisa
Sent: Tue 11/29/2016 6:40:29 PM
Subject: RE: Re:NOTE INSTRUCTIONS!!!!!!!! Second set of translation forms & documents for EPA-FDA fish advice
Fish Advice Qs and As -for translation REVISED.docx
Translation Request Form2-fish advice Q and A REVISED.pdf

I asked Lina the same question yesterday and here is what she replied, although it doesn't make sense:

The word count is the same in English. You could send a new form amending the info to include the additional languages or perhaps notify Sonia to relay the info via email to the Brittany Martinez in OCR. I'm not sure if OCR will require a whole new form altogether.

Here is what I propose. I've revised the word count on the form. Sonia, now you can email the revised Q&A file and revised form with updated word count to Brittany Martinez with a note explaining that we added "in English" to external web links that won't be translated and updated the word count.

Revised files attached (with Cara's website comment stripped out since that was just for our benefit).

From: Lalley, Cara
Sent: Tuesday, November 29, 2016 12:11 PM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Re:NOTE INSTRUCTIONS!!!!!!!! Second set of translation forms & documents for EPA-FDA fish advice

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Subject: RE: Re:NOTE INSTRUCTIONS!!!!!!!! Second set of translation forms & documents for EPA-FDA fish advice

Lisa and Cara,

I didn't see a response to Lina's email. I'm checking in with you……Sonia

From: Younes, Lina
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Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
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(in English)

For example technical page (in English).

sortable table (in English)

2005 FDA survey (in English)

and the results are available in English on FDA's website:
http://www.fda.gov/food/foodborneillnesscontaminants/pesticides/ucm2006797.htm;
http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/ucm184293.htm.

Also see EPA's website for fish consumption advisories in English: http://www2.epa.gov/choose-fish-and-shellfish-wisely

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202-494-4419-cell

younes.lina@epa.gov

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Twitter.com/epaespanol

From: Altieri, Sonia
Sent: Tuesday, November 22, 2016 4:47 PM
To: Language Services Contracts Request; Younes, Lina
Cc: Larimer, Lisa; Lalley, Cara; Christensen, Christina; Loop, Travis
Subject: Second set of translation forms & documents for EPA-FDA fish advice

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Subject: Second set of translation forms & documents for EPA-FDA fish advice

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U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Younes, Lina[Younes.Lina@epa.gov]
From: Larimer, Lisa
Sent: Mon 11/28/2016 5:10:50 PM
Subject: RE: Re:NOTE INSTRUCTIONS!!!!!!!! Second set of translation forms & documents for EPA-FDA fish advice

Sorry, one quick question – do I need to resubmit the forms with the new word counts?

From: Younes, Lina
Sent: Wednesday, November 23, 2016 9:32 AM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>; Language Services Contracts Request <Language_Services_Contracts_Request@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
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sortable table (in English)

2005 FDA survey (in English)

and the results are available in English on FDA's website:
http://www.fda.gov/food/foodborneillnesscontaminants/pesticides/ucm2006797.htm;
http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/ucm184293.htm.

Also see EPA's website for fish consumption advisories in English: http://www2.epa.gov/choose-fish-and-shellfish-wisely

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younes.lina@epa.gov

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Twitter.com/epaespanol

From: Altieri, Sonia
Sent: Tuesday, November 22, 2016 4:47 PM
To: Language Services Contracts Request; Younes, Lina
Cc: Larimer, Lisa; Lalley, Cara; Christensen, Christina; Loop, Travis
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To: Altieri, Sonia <Altieri.Sonia@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
Subject: Second set of translation forms & documents for EPA-FDA fish advice

Sonia,

Here are the forms requesting translations in the other languages.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wilcut, Lars[Wilcut.Lars@epa.gov]
From: Larimer, Lisa
Sent: Mon 11/28/2016 5:09:41 PM
Subject: FW: Second set of translation forms & documents for EPA-FDA fish advice

Ha ha! I win!

From: Younes, Lina
Sent: Monday, November 28, 2016 12:01 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Re: Second set of translation forms & documents for EPA-FDA fish advice

Very good points. Let's go with Ex. 5 - Deliberative Process at this time.

From: Larimer, Lisa
Sent: Monday, November 28, 2016 11:58:41 AM
To: Younes, Lina
Subject: RE: Second set of translation forms & documents for EPA-FDA fish advice

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Happy to do it, of course, if you feel it's needed.

From: Younes, Lina
Sent: Monday, November 28, 2016 10:49 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Re: Second set of translation forms & documents for EPA-FDA fish advice

Well, it's not as simple. Some words are different.

The issue is that Ex. 5 - Deliberative Process nowadays,

But for the older generation Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

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younes.lina@epa.gov

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Twitter.com/epaespanol

From: Larimer, Lisa
Sent: Monday, November 28, 2016 10:46:32 AM
To: Younes, Lina
Subject: RE: Second set of translation forms & documents for EPA-FDA fish advice

Here's where I could use your help. Can someone who normally reads Ex. 5 - Deliberative Process also read Ex. 5 - Deliberative Process? (I think of it being similar to cursive and print English, in a way.)

From: Younes, Lina
Sent: Monday, November 28, 2016 10:42 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Language Services Contracts Request <Language_Services_Contracts_Request@epa.gov>; Altieri, Sonia <Altieri.Sonia@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
Subject: Re: Second set of translation forms & documents for EPA-FDA fish advice

No Ex. 5 - Deliberative Process ?

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younes.lina@epa.gov

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From: Larimer, Lisa
Sent: Monday, November 28, 2016 10:38:32 AM
To: Language Services Contracts Request; Altieri, Sonia; Younes, Lina
Cc: Lalley, Cara; Christensen, Christina; Loop, Travis
Subject: RE: Second set of translation forms & documents for EPA-FDA fish advice

Ex. 5 - Deliberative Process

Thanks!

From: Martinez, Brittany **On Behalf Of** Language Services Contracts Request
Sent: Wednesday, November 23, 2016 9:29 AM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>; Younes, Lina <Younes.Lina@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
Subject: Re: Second set of translation forms & documents for EPA-FDA fish advice

Hi all-

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To: Language Services Contracts Request; Younes, Lina
Cc: Larimer, Lisa; Lalley, Cara; Christensen, Christina; Loop, Travis
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Sonia

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U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Younes, Lina[Younes.Lina@epa.gov]
From: Larimer, Lisa
Sent: Mon 11/28/2016 4:58:42 PM
Subject: RE: Second set of translation forms & documents for EPA-FDA fish advice

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younes.lina@epa.gov

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☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Younes, Lina[Younes.Lina@epa.gov]
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Sent: Mon 11/28/2016 3:46:33 PM
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1200 Pennsylvania Ave., NW, RM 2513-K

William Jefferson Clinton North --Mail Code: 1703A
Washington, DC 20460
202-564-9924-office

202-494-4419-cell

younes.lina@epa.gov

Visit EPA's Spanish website: espanol.epa.gov
Facebook.com/epaespanol
Twitter.com/epaespanol

From: Larimer, Lisa
Sent: Monday, November 28, 2016 10:38:32 AM
To: Language Services Contracts Request; Altieri, Sonia; Younes, Lina

Cc: Lalley, Cara; Christensen, Christina; Loop, Travis
Subject: RE: Second set of translation forms & documents for EPA-FDA fish advice

Ex. 5 - Deliberative Process

Thanks!

From: Martinez, Brittany **On Behalf Of** Language Services Contracts Request
Sent: Wednesday, November 23, 2016 9:29 AM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>; Younes, Lina <Younes.Lina@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
Subject: Re: Second set of translation forms & documents for EPA-FDA fish advice

Hi all-

Both requests have been approved. The contractor has asked the following for your language needs:

Ex. 5 - Deliberative Process

From: Altieri, Sonia
Sent: Tuesday, November 22, 2016 4:47:44 PM

To: Language Services Contracts Request; Younes, Lina
Cc: Larimer, Lisa; Lalley, Cara; Christensen, Christina; Loop, Travis
Subject: Second set of translation forms & documents for EPA-FDA fish advice

Attached are the additional translation requests for the EPA-FDA fish advice (Languages: **Ex. 5 - Deliberative Process**). This material is for U.S. communities.

Please let us know if these requests are approved by the LEP Executive Order. If you have any questions, please let me know. As always, thank you for your assistance! Happy Thanksgiving!
Sonia

From: Larimer, Lisa
Sent: Tuesday, November 22, 2016 1:56 PM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
Subject: Second set of translation forms & documents for EPA-FDA fish advice

Sonia,

Here are the forms requesting translations in the other languages.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Tue 11/22/2016 9:52:56 PM
Subject: FYI: Ex. 5 - Deliberative Process are approved

From: Younes, Lina
Sent: Tuesday, November 22, 2016 4:50 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Martinez, Brittany <Martinez.Brittany@epa.gov>; Altieri, Sonia <Altieri.Sonia@epa.gov>
Subject: Re: Translation forms & documents for EPA-FDA fish advice

Just to reconfirm. I approve the translation of the EPA-FDA announcement materials into **Ex. 5 - Deliberative Process** in the United States.

Lina Younes
Multilingual Communications Liaison
Office of Web Communications
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW, RM 2513-K

William Jefferson Clinton North --Mail Code: 1703A
Washington, DC 20460
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202-494-4419-cell

younes.lina@epa.gov

Visit EPA's Spanish website: espanol.epa.gov
Facebook.com/epaespanol
Twitter.com/epaespanol

From: Larimer, Lisa
Sent: Tuesday, November 22, 2016 4:40:50 PM
To: Younes, Lina
Cc: Martinez, Brittany
Subject: RE: Translation forms & documents for EPA-FDA fish advice

Ex. 5 - Deliberative Process was included with the Ex. 5 - Deliberative Process request. The email you sent said you were approving the Ex. 5 - Deliberative Process but wanted more information on Ex. 5 - Deliberative Process which we discussed.

From: Younes, Lina
Sent: Tuesday, November 22, 2016 2:42 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Martinez, Brittany <Martinez.Brittany@epa.gov>
Subject: Re: Translation forms & documents for EPA-FDA fish advice

I'm not sure I saw the first form. But I'll approve it.

Lina Younes

Multilingual Communications Liaison

EPA Office of Web Communications

202-564-9924

younes.lina@epa.gov

Facebook.com/epaespanol

Twitter.com/epaespanol

On Nov 22, 2016, at 2:24 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

> I've submitted another form for the additional languages we discussed, so you should be receiving that soon. Wondering if you have approved or will approve the Ex. 5 - Deliberative Process request.
>
> -Lisa
>
> **From:** Younes, Lina

Sent: Friday, November 18, 2016 4:14 PM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>; Language Services Contracts Request <Language_Services_Contracts_Request@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
Subject: Re: Translation forms & documents for EPA-FDA fish advice

I've approved the translation of this document into Ex. 5 - Deliberative Process, but would like further clarification of the choice of Ex. 5 - Deliberative Process. May consider approving for Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

See attached.

Furthermore, There are individuals who are LEP in the U.S. who speak Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

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Office of Web Communications
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younes.lina@epa.gov

Visit EPA's Spanish website: espanol.epa.gov
Facebook.com/epaespanol

Twitter.com/epaespanol

From: Altieri, Sonia
Sent: Friday, November 18, 2016 3:58:38 PM
To: Language Services Contracts Request
Cc: Larimer, Lisa; Lalley, Cara; Christensen, Christina; Loop, Travis; Younes, Lina
Subject: Translation forms & documents for EPA-FDA fish advice

Attached are the translation requests for the EPA-FED fish consumption advice. Based on previous conversations, this request meets the criteria of the LEP Executive Order. Please let me know if this is the case and if you have any questions. Thanks so much! Sonia

From: Larimer, Lisa
Sent: Friday, November 18, 2016 11:53 AM
To: Altieri, Sonia <Altieri.Sonia@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
Subject: Translation forms & documents for EPA-FDA fish advice

Hi Sonia,

Cara Lalley is out of the office today, so I'm sending these to you directly. Attached are the forms requesting translation of two documents into Ex. 5 - Deliberative Process, and the documents themselves: text for a chart and Q&A. Please let me know if you need anything else. I am teleworking today at Ex. 6 - Personal Privacy

---

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Younes, Lina[Younes.Lina@epa.gov]
Cc: Martinez, Brittany[Martinez.Brittany@epa.gov]; Altieri, Sonia[Altieri.Sonia@epa.gov]
From: Larimer, Lisa
Sent: Tue 11/22/2016 9:52:24 PM
Subject: RE: Translation forms & documents for EPA-FDA fish advice

Thank you!

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Sent: Tuesday, November 22, 2016 4:50 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Martinez, Brittany <Martinez.Brittany@epa.gov>; Altieri, Sonia <Altieri.Sonia@epa.gov>
Subject: Re: Translation forms & documents for EPA-FDA fish advice

Just to reconfirm. I approve the translation of the EPA-FDA announcement materials into Ex. 5 - Deliberative Process for LEP Ex. 5 - Deliberative Process speakers in the United States.

Lina Younes
Multilingual Communications Liaison
Office of Web Communications
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW, RM 2513-K

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Lina Younes

Multilingual Communications Liaison

EPA Office of Web Communications

202-564-9924

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Hi Sonia,

Cara Lalley is out of the office today, so I'm sending these to you directly. Attached are the forms requesting translation of two documents into Ex. 5 - Deliberative Process and the documents themselves: text for a chart and Q&A. Please let me know if you need anything else. I am teleworking today at Ex. 6 - Personal Privacy.

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
Cc: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Larimer, Lisa
Sent: Mon 10/24/2016 1:46:44 PM
Subject: RE: Seafood Advice Update

I can send the briefing materials later this morning.

From: Conerly, Octavia
Sent: Monday, October 24, 2016 9:44 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Subject: FW: Seafood Advice Update

Lisa,

Do we have something for Joel (some pre-brief material) to give to him before Wednesday's meeting with Tom Burke?

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4301T

Room 5233U

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Campbell, Ann

Sent: Monday, October 24, 2016 9:34 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Conerly, Octavia <Conerly.Octavia@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>
Subject: RE: Seafood Advice Update

Betsy, we were able to add Joel to the briefing with Tom but since your biweekly has been a moving target, Joel will need something in advance to look at before Wednesday's meeting. Any chance you can get him materials/ an update today? He also has a few blocks of time tomorrow if we need to put 30 minutes on the calendar. Let me know.

Thanks,

Ann

From: Beauvais, Joel
Sent: Monday, October 17, 2016 3:52 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>
Subject: RE: Seafood Advice Update

OK, thanks, I heard Ex. 5 - Deliberative Process I think we can defer the briefing until after Tom's (or we could do jointly?). Let's talk process at our biweekly so that I can send something back to Jeremy on this.

From: Southerland, Elizabeth
Sent: Monday, October 17, 2016 3:46 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>
Subject: RE: Seafood Advice Update

The peer reviewers agreed with what we did overall Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process We briefed the Children's Health Office last month, and

Ex. 5 - Deliberative Process We couldn't get on Tom Burke's calendar until October 26 so were waiting to get his response before scheduling a briefing with you. Kacee Deener got all our information a month ago Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process I was going to brief you after we hear from Tom. If you want a briefing earlier, I can schedule one asap.

From: Beauvais, Joel
Sent: Monday, October 17, 2016 3:26 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>
Subject: FW: Seafood Advice Update

Hi, Betsy – Can we reconnect on this some time this week?

Joel

From: Sharp, Jeremy [mailto:Jeremy.Sharp@fda.hhs.gov]
Sent: Monday, October 17, 2016 3:23 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Subject: Seafood Advice Update

Hey Joel,

The ongoing saga of seafood advice continues and I wanted to check in with you on next steps and timelines. But first off, thanks very much for helping us get the peer review process done. Now we just have to nail down responding to the peer review.

I understand that the FDA/EPA work group have completed their review of the peer review comments, that they have incorporated the advice from the peer reviewers, and that the document is under review in EPA.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

If it would be helpful, I'm happy to arrange for us to connect or for us to get our food team leadership together with key folks at your end – only if that is helpful of course.

Thanks again for getting us to this point,

Jeremy

Jeremy Sharp

Deputy Commissioner

Policy, Planning, Legislation, and Analysis

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, Maryland 20993

301-796-8770

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Larimer, Lisa
Sent: Thur 10/20/2016 3:19:55 PM
Subject: RE: Revised Fish Advice Documents

thanks

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, October 20, 2016 10:01 AM
To: Jones, William <William.Jones@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Revised Fish Advice Documents

I made the change to Ex. 5 - Deliberative Process as requested.

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Jones, William
Sent: Wednesday, October 19, 2016 4:24 PM
To: Larimer, Lisa; Smegal, Deborah
Subject: RE: Revised Fish Advice Documents

Ex. 5 - Deliberative Process

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, October 19, 2016 4:05 PM
To: Smegal, Deborah; Jones, William
Subject: RE: Revised Fish Advice Documents

Thanks, Debbie. Alas, another day has gotten away from me and I need to head out early (now).

Regarding this tuna Q&A, can we Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

I eat a lot of tuna, but prefer to eat albacore tuna. Is this okay?

Ex. 5 - Deliberative Process

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Wednesday, October 19, 2016 8:43 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Jones, William <William.Jones@fda.hhs.gov>
Subject: Revised Fish Advice Documents

Hi,

Here are the latest cleaned up documents that address our latest round of comments that I sent you last week.

I realize we still need to discuss Ex. 5 - Deliberative Process

Attached are the following documents:

1) NOA
2) Technical web page
3) Peer Review Response
4) Fish Advice Qs and As
5) Fish Advice Peer Review Summary Report
6) Summary of Response to Public Comment
7) Fish Chart

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Larimer, Lisa
Sent: Thur 10/20/2016 3:15:59 PM
Subject: RE: Revised Fish Advice Documents

Yes, the same address.

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, October 20, 2016 10:06 AM
To: Jones, William <William.Jones@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Revised Fish Advice Documents

Lisa,

I am updating the NOA…is your address the same as Jeff's? 1200 PA av, MS 4305T?

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Jones, William
Sent: Thursday, October 20, 2016 10:01 AM
To: Larimer, Lisa
Cc: Smegal, Deborah
Subject: RE: Revised Fish Advice Documents

Sounds good!

From: Larimer, Lisa <Larimer.Lisa@epa.gov>
Date: October 20, 2016 at 9:24:37 AM EDT
To: Jones, William <William.Jones@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Revised Fish Advice Documents

You get to keep your allowance, Bill. The official word is it's me.

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Wednesday, October 19, 2016 4:25 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Revised Fish Advice Documents

I'm betting my allowance on you.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, October 19, 2016 4:06 PM
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7) Fish Chart

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

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240-402-1818

To: Jones, William[William.Jones@fda.hhs.gov]
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To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]
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Subject: RE: Revised Fish Advice Documents

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From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Wednesday, October 19, 2016 8:43 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Jones, William <William.Jones@fda.hhs.gov>
Subject: Revised Fish Advice Documents

Hi,

Here are the latest cleaned up documents that address our latest round of comments that I sent you last week.

I realize we still need to discuss Ex. 5 - Deliberative Process

Attached are the following documents:

1) NOA

2) Technical web page

3) Peer Review Response

4) Fish Advice Qs and As

5) Fish Advice Peer Review Summary Report

6) Summary of Response to Public Comment

7) Fish Chart

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Wed 10/19/2016 12:52:01 PM
Subject: Needed: New fish advice contact on notice of availability

FDA just sent the FR notice that would announce the fish advice, and I noticed Jeff's name is still the EPA contact. Who shall we put instead?

From: Larimer, Lisa
Location: room change! HQ-Room-WJCW-6124-50pp
Importance: Normal
Subject: fish-beach team meeting
Start Date/Time: Thur 10/13/2016 2:00:00 PM
End Date/Time: Thur 10/13/2016 3:00:00 PM

Agenda & notes

Retreat date - 11/17. Requests for advance interviews coming today or tomorrow.
Fish newsletter - microplastics issue - needs DD/DDD review by next Wed
ORD request to use 2008-09 fish data - ok to use in site-specific sense? Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process
Beach documentation updates - 3 new documents posted. New BEACON update in place this week (est), then new schema will be posted on our website.
Verification tool - NCC meeting this week. Asked for waiver from agency web standards. Had to update certification for system (last done in 2011). [Does Betsy still need to send waiver email? Bill will contact PMO person.]
Shellfish/HABs - Chart with cumulative advisories due to HABs on West coast from NOAA. On east coast, all of northeast is shut down. Lots of articles recently.
QA - Bill will be out of the office next week, along with all QA people.
Fish advice - Meetings with Children's Health Protection and ORD Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process
MOU with FDA - past collaboration on shellfish (see ISSC list), phage (Sharon), mercury fish advice
IG evaluation - Draft report coming soon. They will Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process
Travel budget - Input due this Friday.
NHANES special study - Proposal was submitted on 9/30. Will hear back in December whether NHANES accepted the proposal.
NWIFC meeting - Sam working with Lon on date. Need to discuss internally before the meeting.
CR prioritization - Get requests of immediately needed funds to Lisa.

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Larimer, Lisa
Sent: Wed 10/12/2016 2:01:26 PM
Subject: Fish advice materials + location for meeting today
Fish Advice Qs and As-100516 clearance version.docx
Summary_Table_of_Response_to_Public_comments-100516 clearance version.docx
Peer Review Response-fish advice-100516 clearance version.docx
technical web page-fish advice-100516 clearance version.docx
Fish Advice Peer Review Summary Report-100516 clearance version.docx
FISH_CHART_H_9.22.16.pdf

Hi Kacee,

I think some of these materials were still under development when I sent you items earlier, so I wanted to make sure you had the latest versions (although I got a message from an FDA workgroup member this morning saying their lawyers have suggested additional changes; I haven't heard what they are yet). I am including:

- The fish chart
- The Qs & As
- Technical information (to go on web page)
- Peer review report
- Response to peer review
- Response to public comments (to draft June 2014 version of advice)

Would you prefer meeting in your space or mine? I have an off-site meeting in Bethesda at 2:00. Perhaps it would be most expedient if I exited the Metro and came to your space. My Metro ride last night was twice as long as it usually is. I'll bring your number with me in case I'm running late.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: Larimer, Lisa
Sent: Thur 9/29/2016 10:16:48 PM
Subject: fish advice materials from today's meeting
OCHP briefing-092916.docx
FISH_CHART_H_9.22.16.pdf

To: Gentry, Nathan[Gentry.Nathan@epa.gov]
From: Larimer, Lisa
Sent: Thur 9/29/2016 7:45:53 PM
Subject: RE: Meeting request with Tom Burke re: FDA-EPA fish advice

Yes, Lynn said she was going on vacation. Would you be willing to check with her if she is ok if we meet with Tom without her? I would really like to meet with him before the end of October. The timing of this meeting may affect the release of these materials.

Thanks,

Lisa

From: Gentry, Nathan
Sent: Thursday, September 29, 2016 3:21 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Deener, Kathleen <Deener.Kathleen@epa.gov>
Subject: RE: Meeting request with Tom Burke re: FDA-EPA fish advice

Tom is unavailable the weeks of October 17 and 31, and Lynn is unavailable the week of October 24. I've scheduled this meeting at the first available time, on November 7.

Nathan Gentry

Scheduler for Tom Burke, Lek Kadeli and Bob Kavlock

EPA Office of Research and Development

Phone: 202-564-9084

Fax: 202-565-2430

From: Larimer, Lisa
Sent: Thursday, September 29, 2016 12:22 PM
To: Gentry, Nathan <Gentry.Nathan@epa.gov>
Cc: Deener, Kathleen <Deener.Kathleen@epa.gov>

Subject: Meeting request with Tom Burke re: FDA-EPA fish advice

Hi Nathan,

Kacee suggested I contact you to set up a meeting with Dr. Burke. We would like to have it, if possible, the week of Oct. 17 or 24. The invitees would be:

From ORD – Tom Burke, Kacee Deener, Lynn Flowers

From OW – Elizabeth (Betsy) Southerland, Lisa Larimer

One hour should be sufficient. To help with scheduling Betsy Southerland, I suggest you contact Jeanette Martin, 202-566-0984.

Please let me know of any additional information you may need.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Larimer, Lisa
Location: 41209 RRB
Importance: Normal
Subject: Accepted: EPA-FDA Fish Advice
Start Date/Time: Mon 11/7/2016 9:00:00 PM
End Date/Time: Mon 11/7/2016 9:45:00 PM

To: Flowers, Lynn[Flowers.Lynn@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Larimer, Lisa
Sent: Thur 9/29/2016 4:42:08 PM
Subject: RE: meeting on FDA-EPA fish advice

Have a great vacation!

From: Flowers, Lynn
Sent: Thursday, September 29, 2016 12:42 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>
Subject: RE: meeting on FDA-EPA fish advice

Lisa: I am going on vacation….I can catch up later!

Lynn Flowers, PhD, DABT

Office of Science Policy

US EPA

Washington, DC

202-564-6293

From: Larimer, Lisa
Sent: Thursday, September 29, 2016 12:32 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>
Subject: meeting on FDA-EPA fish advice

Hi,

I'd like to meet on the fish advice. It looks as if all of us aren't available at the same time until 10/20 for half an hour, then 10/27. If possible, I'd like to meet with at least Kacee before then. I'm sending an invitation for Oct. 12. Would you prefer to meet in your space or mine? I'm in

the EPA West building.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Larimer, Lisa
Location: TBD
Importance: Normal
Subject: discuss FDA-EPA fish advice
Start Date/Time: Wed 10/12/2016 8:00:00 PM
End Date/Time: Wed 10/12/2016 9:00:00 PM

To: Gentry, Nathan[Gentry.Nathan@epa.gov]
Cc: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Larimer, Lisa
Sent: Thur 9/29/2016 4:22:09 PM
Subject: Meeting request with Tom Burke re: FDA-EPA fish advice

Hi Nathan,

Kacee suggested I contact you to set up a meeting with Dr. Burke. We would like to have it, if possible, the week of Oct. 17 or 24. The invitees would be:

From ORD – Tom Burke, Kacee Deener, Lynn Flowers

From OW – Elizabeth (Betsy) Southerland, Lisa Larimer

One hour should be sufficient. To help with scheduling Betsy Southerland, I suggest you contact Jeanette Martin, 202-566-0984.

Please let me know of any additional information you may need.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Thur 9/29/2016 3:01:22 PM
Subject: today's briefing w/ OCHP
OCHP briefing-092916.docx

To: larimerl Ex. 6 - Personal Privacy
From: Larimer, Lisa
Sent: Wed 9/28/2016 9:54:51 PM
Subject: file
Major changes to fish advice since 2015 briefings.docx

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Larimer, Lisa
Sent: Wed 9/28/2016 5:02:39 PM
Subject: response to RfD comment by fish advice peer review

Hi Kacee,

Here is what we have in the comment response document at the moment. I welcome any suggestions for changes. I would need it by COB tomorrow.

Comment on Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

FDA-EPA Response:

Ex. 5 - Deliberative Process

This is what the technical information (referred to in our response) currently says:

Ex. 5 - Deliberative Process

To: McRae, Evelyn[McRae.Evelyn@epa.gov]
Cc: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Wed 9/28/2016 2:00:23 PM
Subject: TPs for Sara's general - FDA-EPA fish advice

•□□□□□□ FDA wants to put all the documents (e.g., fish chart, Qs & As, technical info, peer review comment response) into their clearance process this Friday. We are working with them to finalize changes based on peer review.

•□□□□□□ We have a meeting set up with OCHP on Thursday at 4. Lisa sent some materials at staff level yesterday to lay groundwork and see if there are still concerns before the meeting.

•□□□□□□ On a similar note, Lisa has sent materials to Kacee Deener in ORD. Kacee said she would try to call Lisa today about it.

•□□□□□□ The peer review was generally positive, with minor recommendations for improvements. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

This is all I have time to write up!

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Wed 9/28/2016 1:48:07 PM
Subject: RE: UREGENT INFO NEEDED FOR SARA BEFORE 10 AM

Argh, I just saw this!

From: Barash, Shari
Sent: Wednesday, September 28, 2016 8:54 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: McRae, Evelyn <McRae.Evelyn@epa.gov>
Subject: UREGENT INFO NEEDED FOR SARA BEFORE 10 AM

Lisa,

Sara has a general with Betsy S at 10 am and she wants to prep Betsy for OCHP meeting tomorrow on the Fish Advice. She would like some talking points. You can give them to Evelyn McCrae. As I understood, you and FDA were working through final details and it was going well. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Not sure what else would be relevant. If you have a need for Betsy to elevate to get on Tom B's calendar in a timely way, I would make that request through the TPs also.

Shari

Shari Z. Barash

Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 9/27/2016 5:57:52 PM
Subject: RE: Using shared documents

Ok, I'll check later. Thx

From: Wathen, John
Sent: Tuesday, September 27, 2016 1:51 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Using shared documents

My understanding was that the 9.26 version started our meeting yesterday and that the accepted edits constituted a new document. I believe my bullets at the top of page 4 of the undated version that we accepted yesterday were those last edits in that previous version.

~John

From: Larimer, Lisa
Sent: Tuesday, September 27, 2016 1:27 PM
To: Wathen, John <Wathen.John@epa.gov>
Subject: RE: Using shared documents

Thanks, John. Did you also modify the one without a date yesterday? It's showing that you were the last one to modify it.

From: Wathen, John
Sent: Tuesday, September 27, 2016 1:04 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Deborah Smegal (Deborah.smegal@fda.hhs.gov) <Deborah.smegal@fda.hhs.gov>; Bill Jones (William.jones@fda.hhs.gov) <William.jones@fda.hhs.gov>; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov) <Sharon.Natanblut@fda.hhs.gov>
Subject: RE: Using shared documents

I'll consolidate my changes into the version from after the meeting yesterday. They are limited.

It is done. The version labeled Peer Review Response fish advice 9.26.16 is the operative version. There were no other changes than mine to the JWlate version which I have deleted.

My bad.

~John

From: Larimer, Lisa
Sent: Tuesday, September 27, 2016 12:38 PM
To: Deborah Smegal (Deborah.smegal@fda.hhs.gov) <Deborah.smegal@fda.hhs.gov>; Wathen, John <Wathen.John@epa.gov>; Bill Jones (William.jones@fda.hhs.gov) <William.jones@fda.hhs.gov>; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov) <Sharon.Natanblut@fda.hhs.gov>
Subject: Using shared documents

Hi everyone,

The whole point behind putting our documents in a shared folder was so we would have one version of each document that everyone was working from. Please do **not** save the file with a different name! This creates a separate file, and then everyone else doesn't know which one they should be editing. If you are worried about being able to track changes over time, don't be. There's a version history capability – it saves a copy every time the document has been saved.

We now have 3 versions of the peer review response document in the folder, all of which have been changed after we met yesterday. Someone is going to have to reconcile all those. The odds of me having time to do it is virtually nil, and my team is overextended as it is. Do any of you have an available staff person who is handy with Word that could download all 3 versions, combine all changes into one document, and upload it? If you do, let me know the email address

so I can grant access.

Thanks,

Lisa

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 9/27/2016 5:26:56 PM
Subject: RE: Using shared documents

Thanks, John. Did you also modify the one without a date yesterday? It's showing that you were the last one to modify it.

From: Wathen, John
Sent: Tuesday, September 27, 2016 1:04 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Deborah Smegal (Deborah.smegal@fda.hhs.gov) <Deborah.smegal@fda.hhs.gov>; Bill Jones (William.jones@fda.hhs.gov) <William.jones@fda.hhs.gov>; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov) <Sharon.Natanblut@fda.hhs.gov>
Subject: RE: Using shared documents

I'll consolidate my changes into the version from after the meeting yesterday. They are limited.

It is done. The version labeled Peer Review Response fish advice 9.26.16 is the operative version. There were no other changes than mine to the JWlate version which I have deleted.

My bad.

~John

From: Larimer, Lisa
Sent: Tuesday, September 27, 2016 12:38 PM
To: Deborah Smegal (Deborah.smegal@fda.hhs.gov) <Deborah.smegal@fda.hhs.gov>; Wathen, John <Wathen.John@epa.gov>; Bill Jones (William.jones@fda.hhs.gov) <William.jones@fda.hhs.gov>; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov) <Sharon.Natanblut@fda.hhs.gov>
Subject: Using shared documents

Hi everyone,

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We now have 3 versions of the peer review response document in the folder, all of which have been changed after we met yesterday. Someone is going to have to reconcile all those. The odds of me having time to do it is virtually nil, and my team is overextended as it is. Do any of you have an available staff person who is handy with Word that could download all 3 versions, combine all changes into one document, and upload it? If you do, let me know the email address so I can grant access.

Thanks,

Lisa

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Larimer, Lisa
Sent: Mon 9/26/2016 6:27:43 PM
Subject: Draft of peer review report on FDA-EPA fish advice
BPA 17 Fish Advice Peer Review Summary Report_Final.docx

Hi Kacee,

I'm adding to the fish advice-related items that I've sent you. Here is a draft of the peer review report, which FDA received from the contractor that conducted the peer review.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Larimer, Lisa
Sent: Mon 9/26/2016 4:17:48 AM
Subject: Changes to fish advice
Preview summary of peer review comments.docx
FISH_CHART_H_9.22.16.pdf
Major changes to fish advice since Oct 2015 briefing.docx

Hi Kacee,

I'm following up on the voice mail I left you on Friday. Friday got away from me (my daughter broke her ankle at school), but I wanted to get you something to look at while I'm out of the office for most of Monday. I'm including a summary that I ginned up of major changes to the fish advice since we last briefed Dr. Burke in October 2015 and the latest version of the fish chart. The workgroup is still revising other materials. Because I don't have the final version of the peer review document yet that I could send you, I'm sharing a summary of the peer review comments that I had quickly pulled together for my managers when the comments first came in. Please let me know what else I can send you to help, and please let me know if you see areas that are still issues of concern for your group.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Deborah.smegal@fda.hhs.gov[Deborah.smegal@fda.hhs.gov]; William.jones@fda.hhs.gov[William.jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Larimer, Lisa
Sent: Sun 9/25/2016 10:08:34 PM
Subject: Larimer, Lisa has shared 'Fish Advice Qs and As-after peer review'

Newer version of Qs & As, with previous edits from December accepted and new edits from me added.

Open Fish Advice Qs and As-after peer review.docx

See more related to Larimer, Lisa in Delve.

Get the OneDrive mobile app! Available for

To: Deborah.smegal@fda.hhs.gov[Deborah.smegal@fda.hhs.gov]; William.jones@fda.hhs.gov[William.jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Larimer, Lisa
Sent: Sun 9/25/2016 8:49:48 PM
Subject: Larimer, Lisa has shared 'Fish Advice Qs and As-12.24.2015.2'

I also added the Q&As and fish chart to the shared folder. Sorry for the delay - my older daughter broke her ankle at school on Friday, so that scrambled my day's work plans somewhat.

Open Fish Advice Qs and As-12.24.2015.2.docx

See more related to Larimer, Lisa in Delve.

Get the OneDrive mobile app! Available for

To: Deborah.smegal@fda.hhs.gov[Deborah.smegal@fda.hhs.gov]; William.jones@fda.hhs.gov[William.jones@fda.hhs.gov]
Cc: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Larimer, Lisa
Sent: Wed 9/21/2016 9:17:03 PM
Subject: Larimer, Lisa has shared 'FDA-EPA fish advice'

Resending link

Go to FDA-EPA fish advice

Get the OneDrive mobile app! Available for

From: Larimer, Lisa
Location: wiley building--room 2A-023
Importance: Normal
Subject: Accepted: fish advice peer review discussion--in person
Start Date/Time: Mon 9/26/2016 1:00:00 PM
End Date/Time: Mon 9/26/2016 4:00:00 PM

To: Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]; Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 9/21/2016 4:14:59 PM
Subject: Adobe Connect - Invitation to "Fish advice"

Please join me in the following Adobe Connect Meeting.

Meeting Name: Fish advice

Invited By: Samantha Fontenelle

To join the meeting:

http:/ **Ex. 6 - Personal Privacy** ----------

If you have never attended an Adobe Connect meeting before:

Test your connection:
https://epawebconferencing.acms.com/common/help/en/support/meeting_test.htm

Get a quick overview: http://www.adobe.com/products/adobeconnect.html

To: Wathen, John[Wathen.John@epa.gov]; Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]; Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 9/21/2016 2:50:31 PM
Subject: technical appendix with changes discussed on last week's call
technical web page-fish advice after 091316 call-clean.docx

To: Wathen, John[Wathen.John@epa.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 9/21/2016 2:09:05 PM
Subject: RE: revised response to peer review comment documen
Peer Reviewer Summary 9 15 16 dcs mjs jw ll 9-21.docx

I added on what I could really quickly. Booked til 11. Talk to you then.

From: Wathen, John
Sent: Wednesday, September 21, 2016 9:18 AM
To: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: revised response to peer review comment documen

I had a few comments too and did not want to get too far behind Bill.

~John

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Tuesday, September 20, 2016 5:42 PM
To: Jones, William <William.Jones@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: revised response to peer review comment documen

Thanks….

Others feel free to add your suggestions on this version from Bill. Can someone else cross walk the original comments against our paraphrased summary of the comments to make sure there is agreement?

debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Jones, William
Sent: Tuesday, September 20, 2016 5:28 PM
To: Smegal, Deborah; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Cc: Savidge, Matthew
Subject: RE: revised response to peer review comment documen

This is coming together nicely – thanks Debbie! I didn't get a chance to try and fill in any blanks yet, but suggested a few edits along the way while reading through it (during another meeting), so here they are.

From: Smegal, Deborah
Sent: Thursday, September 15, 2016 5:13 PM
To: Jones, William; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Cc: Savidge, Matthew
Subject: revised response to peer review comment documen

Hi,

Attached is the revised the draft response to peer review document that was significantly revised based on team discussion this week. The comments were synthesized by topic, so if you feel we

mis-characterized something please add your suggestions for alternative wording. Please edit in track changes and we can discuss at our meeting next week.

I started to draft responses to get us going and make our meeting more productive. Again, please edit to improve.

Thanks to Matt Savidge, my new ORISE fellow, who assisted in this effort.

Regards,

Debbie

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
Cc: Cursio, Heather[Cursio.Heather@epa.gov]
From: Larimer, Lisa
Sent: Mon 9/19/2016 8:23:28 PM
Subject: RE: IG Report on Mercury in Fish

Will do!

From: Deener, Kathleen
Sent: Monday, September 19, 2016 4:20 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Cursio, Heather <Cursio.Heather@epa.gov>
Subject: RE: IG Report on Mercury in Fish

Thanks Lisa. We have the meeting with the IG on the books for Oct. 5. I'll forward the invite in case you're interested in listening in.

Happy to talk with you about the fish advice workgroup. Can you include Lynn Flowers, too?

Thanks!

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Larimer, Lisa
Sent: Monday, September 19, 2016 4:15 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>

Cc: Cursio, Heather <Cursio.Heather@epa.gov>
Subject: RE: IG Report on Mercury in Fish

Thanks, Kacee. It was my understanding that Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process If there was more than that, and if the call hasn't happened yet, I would be happy to listen in.

On an unrelated note, the EPA-FDA fish advice workgroup has received the peer reviewers comments and is making modifications to the advice based on that input. Would it be possible to meet with you or whoever is interested in ORD to update you all before we brief Tom Burke?

Thanks,

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Deener, Kathleen
Sent: Monday, September 12, 2016 11:23 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Cc: Cursio, Heather <Cursio.Heather@epa.gov>
Subject: RE: IG Report on Mercury in Fish

Betsy – thanks for the chat just now. Lisa – feel free to give me or Heather Cursio a call if you want more information. I'm adding Heather here.

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Southerland, Elizabeth
Sent: Monday, September 12, 2016 11:21 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Cc: Deener, Kathleen <Deener.Kathleen@epa.gov>
Subject: IG Report on Mercury in Fish

ORD will be meeting with the IG to discuss the recommendation that Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process We can attend that meeting if we wish to do so. Just let KC know.

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
Cc: Cursio, Heather[Cursio.Heather@epa.gov]
From: Larimer, Lisa
Sent: Mon 9/19/2016 8:14:40 PM
Subject: RE: IG Report on Mercury in Fish

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Subject: IG Report on Mercury in Fish

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To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Jones, William[William.Jones@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 2/3/2016 9:28:58 PM
Subject: RE: trend analysis for fish data

Thank you!

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Wednesday, February 03, 2016 4:17 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Jones, William <William.Jones@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Subject: trend analysis for fish data

Hi,

Our team (Regis, and Brenna) completed an analysis of mercury concentrations in fish species over time based on Fish Advice category (best, good, avoid). Overall, Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process In addition, the arithmetic mean mercury concentration for each fish species and 95% bootstrap confidence intervals of these means were depicted graphically. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Please let us know if you have any questions.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Larimer, Lisa
Location: DCRoomWest5231L/DC-CCW-OST
Importance: Normal
Subject: Fish-beach team meeting (notes included)
Start Date/Time: Wed 2/3/2016 6:00:00 PM
End Date/Time: Wed 2/3/2016 7:00:00 PM

Call-in: Ex. 6 - Personal Privacy
Conference extension = Ex. 6 - Personal Privacy
Participant code = Ex. 6 - Personal Privacy

Agenda and Notes

- Updating beach grant condition requirements
  - Lisa will set up meeting with team to come up with language options, run those by OGC then beach coordinators, update managers
- Document on NHANES-mercury blood levels: need a "coming" blurb on website & may need to adjust WA to incorporate new data
  - Lisa will get together with Sam on blurb
  - Sam to check if TO can be amended to include new cycle data or if we'll have to wait until next option is exercised (& when that would be)
- Climate change paper
  - Discussion on whether to put hold on WA & wait until after beach conference or de-scope WA and move $ to another WA (such as fish tissue database). Tracy to do the latter.
- Update on 101 briefing scheduling
  - Joel meeting moved to 2/22. Lisa to send draft presentation to team later today. Team to add answers to questions they think Joel may ask in Notes section.
- Fish advice
  - Sharon N. of FDA contacted Betsy S. FDA will write memo re: **Ex. 5 - Deliberative Process** **Ex. 5 - Deliberative Process**
- Follow-up from fish advisory call
  - Sam received selenium question: wet vs dry weight analyses (Joe Beamon = HECD person, Julianne = SHPD person) What is HECD saying in their comment response, assuming they got this comment? Data available? Different endpoint? Acc. to Leanne, you don't usually find Se concentrations in fish high enough to affect human health. Lisa and Sam to work with Lars and Julianne to craft response to Sam's email.
- National Water Quality Monitoring Conference (EPA & USGS)
  - Leanne's topic got accepted as poster; John's talk is wait-listed and accepted as poster. If John can't go, he'd only do SETAC. Lisa and Shari will review travel plan to see if John can go to 3 conferences this year.
- Round robin/updates (e.g., beach notification data, fish tissue studies, progress on getting products reviewed)
  - Ran out of time. Some discussion on whether to make this meeting every week or 90 minutes every other week.
  - Leanne: seminar scheduled for Sam's team on 2/16 for 2 hours. Incorrect responses for lipid data in STORET by CSGOV(?) in 2010 and 2012. Should be corrected within 3 months, possibly less.

To: Robiou, Grace[Robiou.Grace@epa.gov]
From: Larimer, Lisa
Sent: Tue 1/19/2016 7:48:40 PM
Subject: RE: FYI Only: Water articles in the Press

Thanks! **Ex. 5 - Deliberative Process**

From: Robiou, Grace
Sent: Tuesday, January 12, 2016 10:17 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Subject: Fwd: FYI Only: Water articles in the Press

See second article. Congrats!!!

Begin forwarded message:

From: "Bravo, Antonio" <Bravo.Antonio@epa.gov>
Date: January 12, 2016 at 8:11:20 AM EST
To: OW-OWOW-EVERYONE <OWOWOWEVERYONE@epa.gov>
Subject: FYI Only: Water articles in the Press

Daily News

States Say Sierra Club Lacks 'Harm' To Justify CWA Rule Suit Intervention

Posted: January 11, 2016

A coalition of 14 states is fighting Sierra Club's bid to intervene in the states' lawsuit over EPA and the Army Corps of Engineers' joint Clean Water Act (CWA) jurisdiction rule, saying environmentalists lack legal standing to win a role in the litigation because they cannot show more than "speculative" harm from the agencies' regulation.

The legal fight over the rule is ongoing at the same time as lawmakers push legislation that would undo the policy. The House is expected to vote later this week to approve a Congressional Review Act (CRA) resolution to scrap

the CWA rule, though President Obama has previously issued veto threats over bills targeting the rule.

EPA and the Corps issued the rule last year in order to resolve confusion about the law's reach following Supreme Court rulings that created competing tests for jurisdiction. But GOP lawmakers and industry groups say the rule is a vast regulatory overreach, while some environmentalists say that the rule is not expansive enough.

The CWA is unclear on whether challenges to the rule must be filed in either federal district or appellate courts, and myriad lawsuits over the rule are pending in both. The U.S. Court of Appeals for the 6th Circuit is crafting a decision on whether it has authority to hear consolidated challenges to the rule, and has stayed implementation of the policy nationwide in the interim. If the court takes the cases, it would moot a slew of district court suits.

But if the 6th Circuit decides that the challenges must be heard first in district court, that would shift attention to the lower court suits -- including the case filed by the 14 states in which Sierra Club wants to intervene.

The states in a Jan. 8 opposition brief urge the U.S. District Court for the District of South Dakota's Southeastern Division to reject intervention.

They argue that Sierra Club's motion is untimely because it was filed nearly six months after the start of the district court case, that it cannot overcome the legal presumption that the federal agencies involved in the suit adequately represent their own interests, and that allowing intervention would unduly delay the litigation.

"Although Plaintiff States do not believe any Sierra Club participation is warranted, if the Court were to allow Sierra Club to participate in this case, it should condition such participation or limit Sierra Club's to participation to *amicus curiae*," says the brief.

Legal Standing

Sierra Club is seeking to intervene in *State of North Dakota, et al., v. EPA, et al.*, on behalf of EPA and the Army Corps of Engineers because it is pushing a broad interpretation of EPA's authority under the law to justify a regulation broader than the one the agency finalized.

But the states in the suit are arguing that Sierra Club cannot establish "Article III" legal standing, which requires that a party must show "injury in

fact," a causal link between that injury and the conduct at issue, and that a favorable decision is likely to redress the injury.

The states argue in the brief that Sierra Club's asserted injures, including that its members have "concrete interests in specific water bodies" that injunctive relief for the plaintiff states would strip of protections afforded by the rule, are "speculative" and cannot satisfy the required elements of standing.

"Sierra Club's claims are flawed because none of its members claim a sufficient interest in any waters at issue in this litigation -- those waters located in the Plaintiff States," the states argue. "Merely claiming injury to water bodies they care about is insufficient."

The states cite *Lujan v. National Wildlife Federation*, a 1990 Supreme Court decision in which the court held that "vague allegations of a connection between the environmental group members and lands with which they were concerned were not sufficient to convey standing."

In a footnote in the brief, the states point out that Sierra Club's only indication of a member's connection to a plaintiff state is a Sierra Club member in Minnesota who frequently travels to various wildlife refuges and parks throughout the West and Midwest, including North Dakota.

The states involved in the suit are North Dakota, Alaska, Arizona, Arkansas, Colorado, Idaho, Missouri, Montana, Nebraska, Nevada, New Mexico, South Dakota and Wyoming, with Iowa intervening on behalf of the states.

Disapproval Resolution

Meanwhile, House lawmakers are expected to hold a floor vote this week to approve their version of S.J.Res. 22, a CRA disapproval of the CWA rule that cleared the Senate on Nov. 4 in a 53-44 vote.

The CRA gives Congress 60 days after finalization of an agency rule to block it, but a veto from Obama would require two-thirds of Congress to overcome. The administration previously said that the president's senior advisers would recommend a veto of S.J.Res. 22 back when the Senate was poised to vote on it.

A Nov. 3 Statement of Administration Policy on the CRA resolution said it would "nullify years of work and deny businesses and communities the regulatory certainty needed to invest in projects that rely on clean water.

EPA and Army have sought the views of and listened carefully to the public throughout the extensive public engagement process for this rule."

It concluded, "Simply put, S.J. Res. 22 is not an act of good governance. It would sow confusion and invite conflict at a time when our communities and businesses need clarity and certainty around clean water regulation."

While blocking the currently proposed version of the rule could address GOP lawmakers' fears that the rule unlawfully expands the scope of the CWA, it may also bar the Obama administration or a future GOP or Democratic administration from crafting a replacement rule -- despite bipartisan agreement on the need for a definitive rule on the scope of the water law following the high court rulings that created competing tests for jurisdiction.

The law says a rule blocked under the CRA "may not be reissued in substantially the same form, and a new rule that is substantially the same as such a rule may not be issued, unless the reissued or new rule is specifically authorized by a law enacted after the date of the joint resolution disapproving the original rule."

Congress has only used the CRA successfully once before to undo a Clinton-era workplace ergonomics rule, and votes on other EPA rules have failed. For example, senators in a 53-46 vote in June 2012 rejected Sen. James Inhofe's (R-OK) CRA resolution to disapprove EPA's air toxics rule for power plants. -- *Bridget DiCosmo*

Daily News

Federal Dietary Guidelines Encourage Low-Mercury Fish Consumption

Posted: January 11, 2016

Newly released federal dietary guidelines encourage the public to increase its consumption of fish while also for the first time informing that fish species vary in the level of beneficial oils and harmful methylmercury they contain, picking up on draft advice EPA and the Food and Drug Administration (FDA) issued in 2014.

The finalized Dietary Guidelines for Americans (DGA), released Jan. 7, largely sidesteps the controversial advice an advisory panel gave to the Department of Health and Human Services (HHS) and U.S. Department of

Agriculture (USDA), where the advisors urged HHS and USDA to encourage EPA and FDA to reconsider their draft advice on tuna consumption. Tuna is one of the most commonly eaten fish in the U.S.

Instead, the DGA, which supersedes other federal guidance, repeats its 2010 advice, which for the first time set a floor for the amount of fish that Americans should eat on a weekly basis. The latest report reiterates that pregnant women, should eat no less than 8 ounces of fish per week, while not exceeding 12 ounces of fish per week.

New however, is the DGA's recognition that different seafood species contain different levels of methylmercury and varying amounts of beneficial oils. "For the general population, consumption of about 8 ounces per week of a variety of seafood, which provide an average consumption of 250 mg per day of [eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)], is associated with reduced cardiac deaths among individuals with and without preexisting [cardiovascular disease]," the DGA advises. "Similarly, consumption by women who are pregnant or breastfeeding of at least 8 ounces per week from seafood choices that are sources of DHA is associated with improved infant health outcomes."

The DGA continues by noting that "[w]omen who are pregnant or breastfeeding should consume at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in methylmercury. Obstetricians and pediatricians should provide guidance on how to make healthy food choices that include seafood. Women who are pregnant or breastfeeding and young children should not eat certain types of fish that are high in methylmercury."

The guidelines simplify the 2014 draft advisory from EPA and FDA that sought to balance EPA's traditional concerns that fish can be contaminated with methylmercury, a neurotoxin particularly potent to the developing fetus, with FDA's efforts to encourage women to eat more fish because the lean protein provides beneficial oils like Omega 3s and DHA that boost brain and eye development in the fetus.

The DGA, issued by HHS and USDA, is aimed at broadly advising all Americans on how to eat a healthy diet. It is also used to establish public school lunch menus and which foods are covered as part of federal consumer food subsidy programs.

Dietary Guidelines

Last year the Dietary Guidelines Advisory Committee (DGAC) suggested, based on FDA modeling, that EPA and FDA could increase the amount of albacore tuna that would be safe for these women to eat up to six ounces per week -- advice that horrified environmentalists and public health groups concerned with the amounts of mercury albacore tuna.

At a hearing last March, for example, William Wallace of Consumers Union urged the committee to recommend that EPA and FDA advise "that pregnant women eat no tuna." And in a June statement, several groups argued the DGAC's advice on consumption of albacore tuna would pose risks to children.

Tuna "is by far the largest source of mercury in the American diet, accounting for an estimated 45 percent of all mercury exposure," the groups said. "Albacore tuna has three times more mercury than light tuna and is therefore an unhealthy choice for pregnant women and children."

By contrast, the tuna industry at the March hearing reiterated the DGAC's advice, and some 29 senators in a letter to the FDA Commissioner Stephen Ostroff last April also encouraged reconsidering the albacore tuna limit, based on the DGAC's report.

The latest DGA does not list any species to avoid, as EPA and FDA do, but it does cite the general principles of those agencies' advice.

For the first time, the DGA lists specific types of seafood to recommend as high in beneficial oils and low in mercury -- not including any kind of tuna. "Seafood choices higher in EPA and DHA but lower in methylmercury are encouraged. Seafood varieties commonly consumed in the United States that are higher in EPA and DHA and lower in methylmercury include salmon, anchovies, herring, shad, sardines, Pacific oysters, trout, and Atlantic and Pacific mackerel (not king mackerel, which is high in methylmercury)."

A source with the Environmental Working Group cautiously praised the new advice. The DGA "gives some idea of the complexity to seafood advice, notably the best things [to eat] . . . it's a good list and it doesn't include tuna," the source says. "Some of it is so basic [what we've asked for and that] EPA and FDA avoided doing."

The source compared the DGA advice favorably to the 2014 draft advisory from EPA and FDA. "Compared to the EPA-FDA advice, this is an improvement," the source said. "It conveys some of the differences in the fish species. It gives a clear list [of recommended fish] and clear advice on

numerical [limits]. But, the source adds, the advice is "weak on mercury," noting that it does not provide a list of fish to avoid.

The fishing industry is also touting the new DGA advice, though it also does not mention tuna. "When it comes to seafood the DGA's are clear -- seafood is called out over and over again as a food to encourage," a spokesman for the National Fisheries Institute says. "The DGA's do call for Americans to eat at least 8 [ounces] of fish per week to get the benefits but they also call on pregnant women to eat 8-12 ounces. This is significant because the FDA reports that currently pregnant women eat only 1.89 [ounces] a week, which means now they're missing out on the benefits of seafood." -- *Maria Hegstad* (mhegstad@iwpnews.com)

Daily News

Report Cites Chemical Spill To Highlight Water Privatization Shortcomings

Posted: January 11, 2016

A think tank that often works with environmental groups is pointing to the failures of a West Virginia drinking water utility to both prevent and respond to the 2014 Elk River chemical spill as an example of the problems with utility privatization, and is calling on the state to return control of drinking water systems to municipalities.

A Jan. 7 report from the Civil Society Institute's Boston Action Research concludes that West Virginia American Water (WVAW), a subsidiary of the American Water Company, was unprepared for the Jan. 9, 2014, incident, where a tank owned by Freedom Industries holding 4-methylcyclohexane methanol ruptured and spilled more than 5,000 gallons of the hazardous substance into the Elk River.

Furthermore, the report says that two years after the spill, the utility remains unprepared for a future emergency -- and its lack of preparedness underscores and highlights shortcomings of all American Water Company holdings as well as privatized water utility models in general.

Environmental groups and some water utilities have long been critical of the privatization of public water systems, most recently in the context of public-private partnerships that have been a key part of the Obama administration and water industry's strategy for mitigating the effects of dwindling federal dollars for billions in water infrastructure needs.

EPA officials, including former *de facto* water chief Ken Kopocis have tried to assure groups that these new initiatives are not intended to replace federal funding mechanisms like state revolving funds.

The recent report concludes that an "infusion of federal taxpayer dollars seems almost inevitable to upgrade the country's water infrastructure."

"In the broader scheme of things, it appears that the competition for public dollars between public and private water companies will increase, as local political and private industry pressure for federal taxpayer dollars mounts," researchers write. "This once again begs the question of why the public should support private water utility profit margins when public ownership and management can accomplish this more efficiently and inexpensively."

Looking specifically at West Virginia, the think tank says "the Freedom Industries chemical spill of January 9, 2014 shows how unprepared the company is to deal with disasters," noting that the spill left about 300,000 customers without water for as many as nine days.

"Customer experience with West Virginia American Water is similar to the experience of other American Water Company customers around the country. Indeed, the inadequate and widely criticized operations of private water companies globally have fomented a movement to remunicipalize privatized water utilities," it adds.

The report finds that WVAW violated "numerous regulations" after the 2014 spill, and has spent too much of its resources on "dividend payments" to investors that could "otherwise be invested in the system."

"The situation with WVAW reflects why privatization of water systems has failed. The failure of privatization is attributed to excessive costs, poor service quality, lack of transparency, workforce cuts, and under-investment, among other things," the report says.

To remedy the system's failings, the group recommends that the state assume public ownership and operation of the Charleston, WV, Regional Water system, arguing that a publicly run system "would emphasize water service, security, and safety over profit margin" and that "transparency would be enhanced." WVAW could do this by potentially negotiating a "takeover" if it were willing to sell, or state municipalities could seek to use eminent domain, the report says. -- *Amanda Palleschi* (apalleschi@iwpnews.com)

Everyone's pointing fingers over the water crisis in Flint,...	01/12/2016	Atlanta Journal-Constitution Online	GA
Finger-pointing over toxic tap water in Flint, Michigan	01/11/2016	CNNMoney.com	NY
King: Water crisis in Flint, Mich., is environmental racism	01/11/2016	Daily News Online	NY
Snyder may ask lawmakers for money for Flint crisis	01/11/2016	Detroit Free Press Online	MI
Appeals court upholds large livestock farm regulation	01/10/2016	Blade, The	OH
Stormwater Project To Aid Entire Bay	01/10/2016	Providence Journal, The	RI
TINY LA BELLE PLANS BIG FIGHT AGAINST MORE COAL ASH DUMPING	01/10/2016	Pittsburgh Post-Gazette	PA

News Headline: Everyone's pointing fingers over the water crisis in Flint,... |

Outlet Full Name: Atlanta Journal-Constitution Online
News Text: ...and decreased IQs. (Video via NBC) The U.S. Justice Department and the Environmental Protection Agency have stepped in to...

News Headline: Finger-pointing over toxic tap water in Flint, Michigan |

Outlet Full Name: CNNMoney.com
News Text: ...of Enviromental Quality The U.S. Attorney in Michigan and the federal Environmental Protection Agency are also...

News Headline: King: Water crisis in Flint, Mich., is environmental racism |

Outlet Full Name: Daily News Online
News Text: The public water in Flint, Mich., is so toxic, so dangerous, that tests confirmed it had over 900 times the EPA limit for lead particles.

News Headline: Snyder may ask lawmakers for money for Flint crisis |

Outlet Full Name: Detroit Free Press Online
News Text: ...by Snyder, the U.S. Attorney's Office in Detroit is assisting the U.S. Environmental Protection Agency with an investigation....

News Headline: Appeals court upholds large livestock farm regulation |

Outlet Full Name: Blade, The
News Text: Jan. 11--The U.S. Sixth Circuit Court of Appeals in Cincinnati has upheld a lower court's decision in a case regarding large livestock farms that fall in the concentrated animal feeding operations category, affirming state and federal regulatory agencies cannot be sued for violating federal Clean Water Act permitting procedures they oversee.

The lawsuit was brought in 2014 by Wood County farmers Vickie and Larry Askins of Cygnet shortly after the algae-induced Toledo water crisis in August of that year left nearly 500,000 people with unsafe tap water for three days.

The couple challenged the Ohio General Assembly's controversial 2000 decision -- effective March, 2001 -- to transfer environmental permitting of large livestock farms from the Ohio Environmental Protection Agency to the Ohio Department of Agriculture.

Ohio would become the first state to do that, but bureaucratic delays appear to have cropped up.

The decision has yet to be finalized by the U.S. EPA, according to the judicial panel, although the couple claimed in their lawsuit that the Ohio EPA immediately transferred many of its responsibilities.

"They're doing 90 percent of the NPDES [National Pollutant Discharge Elimination System] permit, but they've never been approved," Ms. Askins said during a recent interview with The Blade.

She said the couple will be speaking to their attorney about whether to attempt to have the case heard by the U.S. Supreme Court. She said it is a strong case dismissed on a technicality.

The Askins and other large livestock farm critics have likened the proposed transfer to the "fox watching the henhouse," because the state's agriculture department also is in the business of promoting large farming operations.

They used the Clean Water Act's citizen lawsuit provision to make their claim.

But in its opinion, the federal appellate court concurred with a ruling by Judge David Katz of U.S. District Court in Toledo. It said it dismissed the claim against the U.S. EPA, the Ohio EPA, and the state agriculture department "for lack of subject matter jurisdiction."

The Askins couple argued in their appeal that a state agency "can run amok and not one citizen in Ohio can stop the resulting chaos" if the Clean Water Act provision cannot be applied.

The federal appeals court said in its ruling, however, that it "must respect the limited nature of citizen lawsuits under the Clean Water Act."

"If Congress intended the citizen suit to be all encompassing, it would have permitted suit for all violations of the Clean Water Act, rather than specifying limited circumstances," the opinion states.

The judges also concurred that Congress "did not intend to give citizens greater and faster enforcement authority against a state than the U.S. EPA."

The decision was issued weeks after a watchdog group called the Less=More Coalition, in

conjunction with the Michigan chapter of the Sierra Club, issued a Nov. 19 report that claimed large livestock farms in the western Lake Erie watershed received more than $16.8 million in direct payments, cost-shares, and other subsidies from the U.S. Department of Agriculture between 2008 and 2015.

The groups have released an interactive online map that shows the locations of 146 large livestock farms within the western Lake Erie watershed, housing a collective 12 million animals that produce more than 630 million gallons of waste annually.

The report claimed millions of taxpayer dollars continued to be disbursed to large livestock farm operators even as concerns about algal toxins rose after the 2014 Toledo water crisis. Manure generated by those large livestock facilities is believed to be one of the algae sources.

Although it is not known how much of that manure spills from lagoons or leaches into waterways after being applied to crop fields as fertilizer, activists contend there are big risks managing that waste and that it must be done well to protect one of the world's largest sources of fresh drinking water.

Contact Tom Henry at: thenry@theblade.com, 419-724-6079, or via Twitter @ecowriterohio.

News Headline: Stormwater Project To Aid Entire Bay |

Outlet Full Name: Providence Journal, The
News Text: PAWTUCKET

PAWTUCKET \x97 Under gray skies on a recent afternoon, Andrew Silvia stood on the Exchange Street Bridge near City Hall and pointed below to clumps of soapy residue floating on the surface of the Blackstone River.

“It might be coming from an outfall,” Silvia, the city's chief of project development, said as he looked down river. “I'd love to know.”

Silvia doesn't know because Pawtucket has never done a comprehensive assessment of its system of 45 stormwater outfalls that channel runoff carrying contaminants and debris from streets and sidewalks to the city's rivers \x97 and ultimately into Narragansett Bay.

But now with the help of an $83,000 federal grant that will be announced on Monday, Silvia, who is a civil engineer, will oversee the

development of a stormwater master plan that will bring together property ownership data and computerized mapping. It also will include inspections of catch basins and other parts of the citywide drainage system that, in places, date to the 1800s.

“The project is not going to get us all the way to understanding, but it is a vital step,” Silvia said.

Pawtucket occupies a critical place in the upper reaches of the Narragansett Bay watershed. Not only does the Blackstone River flow through the center of Pawtucket, the Ten Mile River also meanders along the east side of the city and the Moshassuck River cuts through the west side. All three ultimately empty into the Bay.

The work in Pawtucket is one of 11 projects in Rhode Island and Massachusetts that are receiving a total of $815,000 in federal funding through a program administered by the Narragansett Bay Estuary Program and the New England Water Pollution Control Commission. The money is coming from the U.S. Environmental Protection Agency and is being awarded from the two-year-old Southeast New England Program for Coastal Watershed Restoration.

All of the projects aim to restore water quality in the Greater Narragansett Bay watershed. They range from stormwater analysis in Avon, Massachusetts, in the far northeast corner of the watershed to work identifying pollution sources in Little Narragansett Bay in Westerly, in the southwest corner.

And all of them, in one way or another, focus on stormwater runoff, which scientists say is one of the leading threats to the cleanliness and clarity of Narragansett Bay and other waterways in the region.

Runoff from storms can carry nutrients, such as nitrates from lawn fertilizers, into water bodies, leading to algae blooms that can cause low-oxygen conditions that wipe out fish and shellfish. Stormwater can also carry pathogens, like those in pet waste, causing high-bacteria counts that close beaches.

Because of those threats, since the Southeast New England Program was created in 2014 through an effort spearheaded in Congress by U.S. Sen. Jack Reed, it has focused on projects that aim to control and treat stormwater runoff.

And because the watershed is an interconnected system that crosses state and community lines, each project can have wide effects, said Tom Borden, director of the Narragansett Bay Estuary Program.

“The projects are local,” he said, ”but they have implications statewide.

The work in Pawtucket fits that characterization perfectly.

“It's at the top of the system,” said Borden.

Silvia said, “All of these waters are impaired. But to the untrained eye, they look beautiful \x97 which speaks to the challenge we face.”

Along with the federal grant, the city is providing a $28,055 match.

The goal is to come up with a list of 10 priority projects to divert and treat runoff that the city could pursue at a later date. They might include the construction of rain gardens, bioswales, artificial wetlands or other types of so-called green infrastructure.

Mayor Donald Grebien credited Silvia and said the grant “will enable Pawtucket to have a truly robust and effective storm water management program.”

Although the Southeast New England Program provides funding for an area from Westerly to Cape Cod, the grants administered by the Narragansett Bay Estuary Program only cover the western half of the region. Another set of grants \x97 for six projects totaling $800,000 in funding \x97 around Buzzards Bay and on the Cape is also set to be announced on Monday by the Buzzards Bay Estuary Program.

The two estuary programs were tasked with administering the grants in the first two years of the initiative, because they work closely with local communities and understand their environmental challenges, said Borden. The EPA will take over the grant program for the 2016 and 2017 funding years when up to $7 million will be available. A request for proposals was

issued last month for the next funding period and the deadline for applications is Jan. 22.

The administration of the grants is changing, he said, but the focus will continue to be on stormwater runoff and its effects.

“Those are the impairments that are a threat to aquatic health,” Borden said.

Silvia, who in a previous job helped develop stormwater plans for universities and private companies, knows that well.

“We who work more closely on this issue see how it ripples through the rest of our lives,” he said.

\x97akuffner @providencejournal.com

(401) 277-7457

On Twitter: @KuffnerAlex

News Headline: TINY LA BELLE PLANS BIG FIGHT AGAINST MORE COAL ASH DUMPING |

Outlet Full Name: Pittsburgh Post-Gazette
News Text: Only about 250 people live in La Belle, a former coal mining patch on an inside bend of the Monongahela River in Luzerne Township, Fayette County. It's so tiny that it doesn't appear on most maps.

But that hasn't stopped coal-fired power plant operators from dumping thousands of tons of coal ash there over the decades, enough to sicken many of the town's residents, according to Jeremy Ulery, who testified at a state Department of Environmental Protection public hearing last week against a permit that would allow the dumping of much more ash there.

"Our cancer rates are high, people are getting sick, and yet the DEP is considering allowing them to bring more of this toxic stuff into places people can't even find on a map," Mr. Ulery said. "They choose towns like ours because they think we don't matter. But let's see them put this stuff in Pittsburgh or Sewickley. Let's see how that goes over."

Mr. Ulery was one of more than a dozen people to vent frustration and anger in testimony against the five-year permit renewal that would allow Matt Canestrale Contracting Inc. to continue discharging wastewater into the Monongahela River from the abandoned strip mine where coal ash waste has been dumped for decades.

Approval of the National Pollutant Discharge Elimination System permit by the DEP would be a step toward allowing the Canestrale company to begin accepting coal ash from FirstEnergy's Bruce Mansfield power plant in Shippingport, Beaver County.

The Akron, Ohio-based electric power company has been ordered by the DEP to close its massive, leaky Little Blue Run coal ash impoundment and has floated a plan to barge the 2.5 million tons of ash it generates a year about 100 miles up the Ohio and Monongahela rivers to La Belle and another ash impoundment near its Hatfield's Ferry power plant in Greene County.

John Purcell, the Luzerne Township solicitor, told DEP regulators that township supervisors strongly opposed the permit and would take legal steps to challenge any new importation of

ash.

"The coal ash refuse pile already dominates the area along the [Monongahela] river and who knows what it's discharging," Mr. Purcell said. "But the big blue elephant in the room is what will happen in the future if more and more fly ash is brought in. So we're going to fight this. We're not going to stand for it here."

Coal ash is produced when coal is burned, and the dusty residue, as fine as talcum powder, contains varying amounts of arsenic, cadmium, lead, selenium, mercury and other metals. Some of those are toxic, others are known to cause cancer. The ash on the Canestrale property can become airborne when it's windy, blowing into the La Belle residential neighborhoods and the nearby prison, State Correctional Institution Fayette.

"There's tremendous frustration here," said Charles Hunnell, a retired Navy commander and high school economics teacher who lives in Waynesburg. "Why should the kids suffer? Why should we suffer? Why should the prisoners suffer? We're being ignored because it's poor."

According to a federal lawsuit filed in June against the Canestrale company by Public Justice and the Environmental Integrity Project, on behalf of the environmental organization Citizens Coal Council, the La Belle ash dump is discharging aluminum, manganese, sulfates and total dissolved solids above Pennsylvania drinking water standards, and is polluting local streams with levels of sulfate and total dissolved solids at levels that can damage fish and other aquatic life.

"This is as clear a case of environmental injustices as you'll find, particularly in the context of SCI-Fayette," said Patrick Grenter, executive director of the Center for Coalfield Justice. "Not only is the health, livelihood and property of the residents at risk, but also the lives of the 2,000 people incarcerated at the prison and the 800 staff. All of them are being held captive in a toxic environment."

Yma Smith said many of her neighbors and friends are sick or have died from cancer or respiratory problems and called on the DEP to conduct a health study of residents before it approves any permit that would allow more dumping.

"My kids deserve better," Ms. Smith said. "I'm tired of going to funeral homes."

While there's no scientific proof that fly ash or other forms of pollution are causing health problems, Luzerne Township has elevated mortality levels for diseases that have been linked to pollution exposure, according to a 2010 Pittsburgh Post-Gazette ecological study on mortality rates. From 2000 through 2008, Luzerne, which includes La Belle, had heart disease mortality that was 26 percent above the national average, and respiratory disease mortality that was 20 percent higher.

Katherine Ulrey said La Belle is home, but she no longer wants to live there after her 8-year-old son missed 27 days of school last year due to respiratory problems and rashes, and her daughter developed breathing problems. She said the coal ash has polluted the air and made the water unsafe to drink.

"I'm buying bottled water because the problems are not just in the air but also the water," Ms. Ulrey said. "It's killing all of us and I can't stand it anymore."

Neither the Canestrale company nor FirstEnergy attended the hearing. Canestrale could not be reached for comment. Jennifer Young, a FirstEnergy spokeswoman, said the company is pursuing "multiple options for reuse or disposal of Bruce Mansfield coal combustion residuals," including the La Belle and Hatfield's Ferry facilities.

Ms. Young said the company has received a state permit that will allow it to use the Hatfield's Ferry site and is awaiting the DEP's decision on a beneficial use permit that will allow it to use coal ash on mine reclamation projects, like La Belle.

Joel Koricich, DEP district mining manager, said the hearing, which he attended, was the last in a series of more than half a dozen meetings held on the water discharge permit, which is also under review by the U.S. Environmental Protection Agency.

A decision on whether to grant the water discharge permit renewal and the state coal refuse disposal permit for the La Belle site is months away, he said.

National Pollutant Discharge Elimination System permits, required by federal and state environmental agencies, establish limits on the amount of pollutants that can be discharged by industrial sources into surface waters, such as the Monongahela River, which flows by La Belle.

Antonio Bravo

Office of Wetlands, Oceans & Watersheds

202-566-1976

To: Martinez, Menchu[martinez.menchu-c@epa.gov]
From: Larimer, Lisa
Sent: Fri 1/15/2016 7:41:37 PM
Subject: RE: FYI: Federal Dietary Guidelines Encourage Low-Mercury Fish Consumption

Thanks!

From: Martinez, Menchu
Sent: Tuesday, January 12, 2016 8:27 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Fw: FYI: Federal Dietary Guidelines Encourage Low-Mercury Fish Consumption

Congratulations

From: Conerly, Octavia
Sent: Tuesday, January 12, 2016 7:46:19 AM
To: OST-EVERYONE
Subject: FYI: Federal Dietary Guidelines Encourage Low-Mercury Fish Consumption

FYI...

Daily News

Federal Dietary Guidelines Encourage Low-Mercury Fish Consumption

Posted: January 11, 2016

Newly released federal dietary guidelines encourage the public to increase its consumption of fish while also for the first time informing that fish species vary in the level of beneficial oils and harmful methylmercury they contain, picking up on draft advice EPA and the Food and Drug Administration (FDA) issued in 2014.

The finalized Dietary Guidelines for Americans (DGA), released Jan. 7, largely sidesteps the controversial advice an advisory panel gave to the Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA), where the advisors urged HHS and USDA to encourage EPA and FDA to

reconsider their draft advice on tuna consumption. Tuna is one of the most commonly eaten fish in the U.S.

Instead, the DGA, which supersedes other federal guidance, repeats its 2010 advice, which for the first time set a floor for the amount of fish that Americans should eat on a weekly basis. The latest report reiterates that pregnant women, should eat no less than 8 ounces of fish per week, while not exceeding 12 ounces of fish per week.

New however, is the DGA's recognition that different seafood species contain different levels of methylmercury and varying amounts of beneficial oils. "For the general population, consumption of about 8 ounces per week of a variety of seafood, which provide an average consumption of 250 mg per day of [eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)], is associated with reduced cardiac deaths among individuals with and without preexisting [cardiovascular disease]," the DGA advises. "Similarly, consumption by women who are pregnant or breastfeeding of at least 8 ounces per week from seafood choices that are sources of DHA is associated with improved infant health outcomes."

The DGA continues by noting that "[w]omen who are pregnant or breastfeeding should consume at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in methylmercury. Obstetricians and pediatricians should provide guidance on how to make healthy food choices that include seafood. Women who are pregnant or breastfeeding and young children should not eat certain types of fish that are high in methylmercury."

The guidelines simplify the 2014 draft advisory from EPA and FDA that sought to balance EPA's traditional concerns that fish can be contaminated with methylmercury, a neurotoxin particularly potent to the developing fetus, with FDA's efforts to encourage women to eat more fish because the lean protein provides beneficial oils like Omega 3s and DHA that boost brain and eye development in the fetus.

The DGA, issued by HHS and USDA, is aimed at broadly advising all Americans

on how to eat a healthy diet. It is also used to establish public school lunch menus and which foods are covered as part of federal consumer food subsidy programs.

Dietary Guidelines

Last year the Dietary Guidelines Advisory Committee (DGAC) suggested, based on FDA modeling, that EPA and FDA could increase the amount of albacore tuna that would be safe for these women to eat up to six ounces per week -- advice that horrified environmentalists and public health groups concerned with the amounts of mercury albacore tuna.

At a hearing last March, for example, William Wallace of Consumers Union urged the committee to recommend that EPA and FDA advise "that pregnant women eat no tuna." And in a June statement, several groups argued the DGAC's advice on consumption of albacore tuna would pose risks to children.

Tuna "is by far the largest source of mercury in the American diet, accounting for an estimated 45 percent of all mercury exposure," the groups said. "Albacore tuna has three times more mercury than light tuna and is therefore an unhealthy choice for pregnant women and children."

By contrast, the tuna industry at the March hearing reiterated the DGAC's advice, and some 29 senators in a letter to the FDA Commissioner Stephen Ostroff last April also encouraged reconsidering the albacore tuna limit, based on the DGAC's report.

The latest DGA does not list any species to avoid, as EPA and FDA do, but it does cite the general principles of those agencies' advice.

For the first time, the DGA lists specific types of seafood to recommend as high in beneficial oils and low in mercury -- not including any kind of tuna. "Seafood choices higher in EPA and DHA but lower in methylmercury are encouraged. Seafood varieties commonly consumed in the United States that are higher in EPA and DHA and lower in methylmercury include salmon, anchovies, herring, shad, sardines, Pacific oysters, trout, and Atlantic and Pacific mackerel (not king

mackerel, which is high in methylmercury)."

A source with the Environmental Working Group cautiously praised the new advice. The DGA "gives some idea of the complexity to seafood advice, notably the best things [to eat] . . . it's a good list and it doesn't include tuna," the source says. "Some of it is so basic [what we've asked for and that] EPA and FDA avoided doing."

The source compared the DGA advice favorably to the 2014 draft advisory from EPA and FDA. "Compared to the EPA-FDA advice, this is an improvement," the source said. "It conveys some of the differences in the fish species. It gives a clear list [of recommended fish] and clear advice on numerical [limits]. But, the source adds, the advice is "weak on mercury," noting that it does not provide a list of fish to avoid.

The fishing industry is also touting the new DGA advice, though it also does not mention tuna. "When it comes to seafood the DGA's are clear -- seafood is called out over and over again as a food to encourage," a spokesman for the National Fisheries Institute says. "The DGA's do call for Americans to eat at least 8 [ounces] of fish per week to get the benefits but they also call on pregnant women to eat 8-12 ounces. This is significant because the FDA reports that currently pregnant women eat only 1.89 [ounces] a week, which means now they're missing out on the benefits of seafood." -- *Maria Hegstad* (mhegstad@iwpnews.com)

Octavia Conerly

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Washington, DC 20460

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PHONE: (202) 566-1094

FAX: (202) 566-0441

To: Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]
From: Larimer, Lisa
Sent: Tue 1/12/2016 10:16:01 PM
Subject: Found an error in table that's going in technical appendix - TA needs slight revision
Fish advice calculations-011216.xlsx

The sortable fish table in the technical appendix needs to have [redacted] for [redacted] I checked linkages and it was just pulling the average for [redacted] not [redacted]

As you can tell, I'm cleaning up the spreadsheet. I think I've gotten as far as I can today, and I need to revise a presentation I'm giving tomorrow morning. If you want to have someone doublecheck my calculations, that's fine, but the overall file will probably change more. I think

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Larimer, Lisa
Sent: Tue 1/12/2016 8:35:03 PM
Subject: RE: Type of peer review for fish advice

Thank you!

From: Deener, Kathleen
Sent: Tuesday, January 12, 2016 3:34 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Type of peer review for fish advice

Hi Lisa – sorry for the delay. We are good with this.

Thanks,

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Larimer, Lisa
Sent: Tuesday, January 12, 2016 11:31 AM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Subject: Type of peer review for fish advice

Hi!

I left you a voice mail but in case you're in back-to-back meetings all day like me I'm also trying to reach you by email.

I'm drafting the cover note for Joel to send to Jeremy. He's requesting I include a description of the "mechanics" of the peer review, and I wanted to make sure our offices were in agreement about what we envision before I send that over.

Here is what was in an attachment Sara Hisel-McCoy sent you late last week. I will summarize the timeline portion for Jeremy (3 ½ - 6 ½ months). Please let me know ASAP if the type of peer review portion is not in alignment with what you were thinking.

Peer Review of Fish Advice

Type of review

Ex. 5 - Deliberative Process

Timeline

Ex. 5 - Deliberative Process

If changes to the advice are needed, add:

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Tue 1/12/2016 4:42:41 PM
Subject: FW: Update on cover note for Joel/Jeremy on fish advice

Typing too fast; meant to cc you

From: Larimer, Lisa
Sent: Tuesday, January 12, 2016 11:42 AM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Subject: Update on cover note for Joel/Jeremy on fish advice

I have a brief cover note ready to go, but am waiting to hear back from KC on agreement on the type of peer review. I left her a voice mail and sent her an email. As soon as I hear back, I'll send you the cover note and attach the peer review charge questions.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Larimer, Lisa
Sent: Tue 1/12/2016 4:30:50 PM
Subject: Type of peer review for fish advice

Hi!

I left you a voice mail but in case you're in back-to-back meetings all day like me I'm also trying to reach you by email.

I'm drafting the cover note for Joel to send to Jeremy. He's requesting I include a description of the "mechanics" of the peer review, and I wanted to make sure our offices were in agreement about what we envision before I send that over.

Here is what was in an attachment Sara Hisel-McCoy sent you late last week. I will summarize the timeline portion for Jeremy (3 ½ - 6 ½ months). Please let me know ASAP if the type of peer review portion is not in alignment with what you were thinking.

Peer Review of Fish Advice

Type of review

Ex. 5 - Deliberative Process

Timeline

Ex. 5 - Deliberative Process

If changes to the advice are needed, add:

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Mon 1/11/2016 6:21:48 PM
Subject: FW: Draft Ex. 5 - Deliberative Process FDA-EPA fish advice

Keeping you in the loop

From: Southerland, Elizabeth
Sent: Monday, January 11, 2016 1:15 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: RE: Draft Ex. 5 - Deliberative Process FDA-EPA fish advice

We have met to discuss your attached draft and have the following revisions we would like you to make before we send on to Joel to send to FDA. Please call me at 202 566 0328 or email if you disagree with any of the revisions below.

Ex. 5 - Deliberative Process

From: Deener, Kathleen
Sent: Monday, January 11, 2016 9:40 AM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: RE: Draft Ex. 5 - Deliberative Process FDA-EPA fish advice

Hi Sara –

Attached are ORD's suggested edits on Ex. 5 - Deliberative Process Please let me know if you have any questions.

Thanks,

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Hisel-Mccoy, Sara
Sent: Monday, January 11, 2016 9:05 AM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: Re: Draft Ex. 5 - Deliberative Process FDA-EPA fish advice

Thanks Kacee. Pls do let us know as soon as you can. Thanks, Sara

Sara Hisel-McCoy

Standards and Health Protection Division

202 566-1649

On Jan 6, 2016, at 5:01 PM, Deener, Kathleen <Deener.Kathleen@epa.gov> wrote:

Thanks Sara. I appreciate it! I'll connect with you on Monday.

Kacee Deener, MPH

Senior Science Advisor

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(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Hisel-Mccoy, Sara
Sent: Wednesday, January 06, 2016 5:01 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: RE: Draft **Ex. 5 - Deliberative Process** FDA-EPA fish advice

KC,

Ex. 6 - Personal Privacy Yes, certainly.

Thank you,
Sara

From: Deener, Kathleen
Sent: Wednesday, January 06, 2016 5:00 PM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: RE: Draft Ex. 5 - Deliberative Process FDA-EPA fish advice

Hi Sara –

Ex. 6 - Personal Privacy I've shared this with a few of the ORD folks who've been involved in our conversations. However, I'd like to talk with Tom about this on Monday morning. Could you wait until next week to send this to FDA?

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Hisel-Mccoy, Sara
Sent: Tuesday, January 05, 2016 1:13 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: Draft Ex. 5 - Deliberative Process FDA-EPA fish advice

KC-

Happy new year! Attached is a draft Ex. 5 - Deliberative Process my staff developed Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Joel told FDA we would send Ex. 5 - Deliberative Process by the end of this week, so we appreciate your assistance in getting Tom's input.

Thanks,

Sara

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Larimer, Lisa
Sent: Thur 1/7/2016 8:37:09 PM
Subject: RE: status of technical doc?
technical web page-fish advice redline- 12 24 2015 (00000002)-LL.docx

Argh. I've been so slammed. I haven't gotten the spreadsheet in a good place yet. Here's the redline of the technical doc.

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, January 07, 2016 12:42 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: status of technical doc?

Hi,

I am supposed to be off tomorrow and was wondering how things are coming on the technical appendix? Also, what is the new cut off for **Ex. 5 - Deliberative Process** We need to update the **Ex. 5 - Deliberative Process**

debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Wathen, John[Wathen.John@epa.gov]
Cc: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Thur 1/7/2016 7:04:01 PM
Subject: FW: Reminder: Joel's weekly Administrator e-mail

John,

Can you write a paragraph for this?

From: Hisel-Mccoy, Sara
Sent: Thursday, January 07, 2016 1:26 PM
To: Conerly, Octavia <Conerly.Octavia@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Lape, Jeff <lape.jeff@epa.gov>; Washington, Evelyn <Washington.Evelyn@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Reminder: Joel's weekly Administrator e-mail

Ahh – just got to this. Let me see what we can put together. Thanks, Sara

From: Conerly, Octavia
Sent: Thursday, January 07, 2016 11:58 AM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Lape, Jeff <lape.jeff@epa.gov>; Washington, Evelyn <Washington.Evelyn@epa.gov>
Subject: RE: Reminder: Joel's weekly Administrator e-mail

Hi Sara,

Matt Klasen has suggested that OST provide any updates (via Joel's weekly email) for the Administrator on the fish advice. Is there anything to report? Heidi has asked that we send our items by 1pm today but if you can't get this to me by then I will let Heidi know we'll be a little late with it.

Octavia Conerly

Special Assistant to the Office Director

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PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Conerly, Octavia
Sent: Thursday, January 07, 2016 8:49 AM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Wood, Robert <Wood.Robert@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Lape, Jeff <lape.jeff@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>; Washington, Evelyn <Washington.Evelyn@epa.gov>; Zipf, Lynn <Zipf.Lynn@epa.gov>
Subject: FW: Reminder: Joel's weekly Administrator e-mail

So far, I have one topic/item for Joel's weekly to the Administrator. These were due yesterday at 1pm. Please let me know if I have missed anything and/or if you have other items as soon as you can. Thanks in advance.

White House Roundtable on Water Innovation (December 15, 2015) and White House Water Summit (March 22, 2016) – On December 15, I attended, along with other members of the EPA Team, the Roundtable on Water Innovation convened by OMB/OSTP/CEQ. The event included over 100 external and federal partners. Several folks remarked about how the Paris Climate Agreement accentuated the water resource issues and how technology enhancements can help address both climate and water impacts.

On March 22, 2016, the Administration will host a **White House Water Summit** to raise awareness of water issues in the United States, and to catalyze ideas and actions to help build a sustainable and secure water future through innovative solutions. This event, which builds on the Roundtable and other Administration activities, will bring together representatives from Federal, state, regional, local and tribal levels, and from other stakeholder groups, to discuss and advance progress in this important area.

As part of this effort, the White House is issuing a call-to-action for individuals, organizations, and institutions from all sectors to take new, specific, and measurable steps to address key water issues, such as drought or flooding; water availability or quality; water-use efficiency; water security; ecosystem requirements; or others. If applicable, announcements of these steps may be incorporated into official materials for the White House Water Summit, and involved individuals may be invited to participate in the White House Water Summit and/or related events.

This event will be an opportunity for EPA to showcase our important role and actions to support sustainable water. Ellen Gilinsky will be facilitating and coordinating EPA's efforts for the White House Water Summit.

Octavia Conerly

Special Assistant to the Office Director

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1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Conerly, Octavia
Sent: Wednesday, January 06, 2016 10:00 AM
To: Wood, Robert <Wood.Robert@epa.gov>; Lape, Jeff <lape.jeff@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>

Cc: Washington, Evelyn <Washington.Evelyn@epa.gov>; Zipf, Lynn <Zipf.Lynn@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: RE: Reminder: Joel's weekly Administrator e-mail

Good morning,

Please submit any items for Joel's weekly email to the Administrator to me **by 1pm today.** See below for Joel's last email to Gina. Thanks in advance.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Bethel, Heidi
Sent: Wednesday, January 06, 2016 9:38 AM
To: Conerly, Octavia <Conerly.Octavia@epa.gov>; Nandi, Romell <Nandi.Romell@epa.gov>; Farris, Erika D. <Farris.Erika@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Ruf, Christine <Ruf.Christine@epa.gov>
Cc: Klasen, Matthew <Klasen.Matthew@epa.gov>; Orvin, Chris <Orvin.Chris@epa.gov>; Lousberg, Macara <Lousberg.Macara@epa.gov>
Subject: Reminder: Joel's weekly Administrator e-mail

Hi All,

Sending along an early reminder this morning to please send any items you may have for Joel's weekly e-mail to the Administrator by noon on Thursday. Let me know if you have any questions. Below is the last e-mail he sent before the end of 2015.

Thank you!

Heidi

Administrator and company – Lots going on but just a few things to report this week. I'll be in the office Monday-Wednesday next week, then out 12/24-12/31 – but available throughout by email or cel.

Regs: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

OR Cadmium, Copper and Aluminum WQS Settlement Discussions: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

ID Arsenic WQS Settlement Discussions: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Fish Advice: We are making some progress with FDA staff on requested changes to and potential peer review of the draft advice; I will be discussing with my FDA counterpart next week. Will look to update you on substance, with Tom Burke, at some point in the near future.

The Drinking Water Mapping Application to Protect Source Waters (DWMAPS): Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Barash, Shari[Barash.Shari@epa.gov]; Wilcut, Lars[Wilcut.Lars@epa.gov]; Vlcan, Manjali[Vlcan.Manjali@epa.gov]
From: Larimer, Lisa
Sent: Thur 1/7/2016 4:10:32 PM
Subject: RE: Topics for general with Sara

For fish advice, I just heard from FDA that their leadership will need to see Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process I don't know if that has been part of the discussion thus far (since no one from OST was there).

I also have one for the future directions retreat next week. I believe we were hoping to invite Betsy S to it. The overview in the morning would probably be the best part. Has anyone reached out to her yet or gotten it on her calendar?

I'll miss the general - another future directions meeting. :-)

Lisa

-----Original Message-----
From: Barash, Shari
Sent: Thursday, January 07, 2016 10:47 AM
To: Wilcut, Lars <Wilcut.Lars@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Vlcan, Manjali <Vlcan.Manjali@epa.gov>
Subject: RE: Topics for general with Sara

Ok, I will add these two and the permits Lean thing.

Shari Z. Barash
Acting Chief
National Branch
Office of Water
US EPA
Washington, DC
202-566-0996
barash.shari@epa.gov

-----Original Message-----
From: Wilcut, Lars
Sent: Thursday, January 07, 2016 9:53 AM
To: Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Vlcan, Manjali <Vlcan.Manjali@epa.gov>
Subject: RE: Topics for general with Sara

We're just getting started on compiling the implementation - related selenium comments but I can talk about the two industry meetings I attended.

Also, HECD is briefing Betsy S. on the missing parameters document (copper BLM) on the 19th, I think. I haven't seen it since we helped them with editing. Has she seen it? Does she have any questions or issues?

From: Barash, Shari
Sent: Thursday, January 7, 2016 7:30 AM
To: Wilcut, Lars; Larimer, Lisa; Vlcan, Manjali
Subject: Topics for general with Sara

Any topics?
I have:
-WQS Ag fact sheet
-Plan for WDD meeting
- PGP update
-Reminder about regional rotations at WQSMA call next week -want to hear her thoughts on Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process idea -share draft Rec Water Conf agenda, tell her about Joel's calendar -report out on marine sanitary survey mtg with PMO -Personnel

Lars -Is there anything on Se we can tell her? Do we know what comments say, did we initiate work on Ex. 5 - Deliberative Process?

Lisa- any thing on Fish Advice or PAMs?

Sent from my iPhone

To: Hisel-Mccoy, Sara[Hisel-McCoy.Sara@epa.gov]
Cc: Barash, Shari[Barash.Shari@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 1/5/2016 6:00:21 PM
Subject: Draft charge questions for peer review of FDA-EPA fish advice
PeerReviewChargeQsDRAFT1-5-16.docx

Draft note for KC

KC-

Happy new year! Attached is a draft list of charge questions my staff came up with Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Joel told FDA we would send the charge questions by the end of this week, so we appreciate your assistance in getting Tom's input.

Thanks,

Sara

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Mon 1/4/2016 7:02:05 PM
Subject: revised charge Qs
PeerChargeQsDFT1-4-16.docx

John,

Given Betsy's (& Sara's in-person) direction below, I've revised the charge questions Ex. 5 - Deliberative Process Can you take a look and let me know what you think? Then I'll informally share it with our MD colleagues before it goes up to Tom & Joel.

From: Hisel-Mccoy, Sara
Sent: Monday, January 04, 2016 10:03 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Fwd: I will be on annual leave Jan 4 thru 8

Sara Hisel-McCoy

Standards and Health Protection Division

202 566-1649

Begin forwarded message:

> **From:** "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
> **Date:** December 29, 2015 at 9:55:40 AM EST
> **To:** "Lape, Jeff" <lape.jeff@epa.gov>, "Ortiz, Agnes" <Ortiz.Agnes@epa.gov>, "Conerly, Octavia" <Conerly.Octavia@epa.gov>, "Martin, Jeanette" <Martin.Jeanette@epa.gov>, "Hisel-Mccoy, Sara" <Hisel-McCoy.Sara@epa.gov>, "Washington, Evelyn" <Washington.Evelyn@epa.gov>, "Wood, Robert" <Wood.Robert@epa.gov>, "Zipf, Lynn" <Zipf.Lynn@epa.gov>, "Behl, Betsy" <Behl.Betsy@epa.gov>, "Flaherty, Colleen" <Flaherty.Colleen@epa.gov>
> **Subject: I will be on annual leave Jan 4 thru 8**
>
> My grandson James Hartigan was born a week early on Dec 28. Mom and baby are doing great. I am so excited! I will be flying to Atlanta to help out and will not be back in the office until Monday Jan 11. I will undoubtedly be off the grid while there, but I will take my iPhone in case I have any free time. The big issue next week is to resolve the charge

questions for the fish advice. I recommend Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Hope everyone is having a great holiday!

Sent from my iPhone

To: Barash, Shari[Barash.Shari@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Mon 12/28/2015 5:28:55 PM
Subject: Fish advice update

I'm doing a quick blitz through email before I get preparations underway for Rich's birthday, and it looks like Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process Am I reading those emails right?

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Jones, William[William.Jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Larimer, Lisa
Sent: Fri 12/18/2015 9:14:38 PM
Subject: RE: Congressional re Fish Advice

I will be out the next two weeks, and John will be out next week after Monday (I think), but let us know if you need any help with the response. I have a lot of things I need to catch up on, so I imagine I'll be checking email occasionally.

-Lisa

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Friday, December 18, 2015 2:54 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Congressional re Fish Advice

FYI: we are supposed to pass responsive language up our chain by 12/28.

William R. Jones, Ph.D.

Deputy Director, Office of Food Safety

Center for Food Safety and Applied Nutrition, USFDA

5100 Paint Branch Parkway

College Park, MD 20740

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
Cc: Dooren, Jennifer[Jennifer.Dooren@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 11/9/2016 6:59:34 PM
Subject: RE: FinalSeafoodConsumptionRelease (4)SMB STM.doc
EPA-FDA Updated Fish Advice_press release_TL+CL.doc

Here is what I've gotten back. Do with it what you will.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, November 07, 2016 11:50 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Subject: RE: FinalSeafoodConsumptionRelease (4)SMB STM.doc

Lisa,

Any word back from your comms person? I would hope that they do not bleed all over it but rather indicate if there are statements they feel require edits. My recollection is that they were very reasonable in 2014 when we drafted the advice and that they quickly reviewed and commented and provided us an EPA quote. Can you please let us know the status of this today?

Thanks.

Sharon

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, November 03, 2016 5:12 PM
To: Natanblut, Sharon
Subject: RE: FinalSeafoodConsumptionRelease (4)SMB STM.doc

Not from me. I figure the comms people will bleed all over it. ☺ I just sent it to the comm person in my office this afternoon.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]

Sent: Thursday, November 03, 2016 4:32 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: FinalSeafoodConsumptionRelease (4)SMB STM.doc

Thanks! Any other press release comments/edits?

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, November 03, 2016 3:11 PM
To: Natanblut, Sharon
Subject: RE: FinalSeafoodConsumptionRelease (4)SMB STM.doc

Press release: The quote on **Ex. 5 - Deliberative Process** isn't something EPA would say, so you'll need to retool that. I'll come up with a quote that you can attribute to Betsy Southerland.

Ex. 5 - Deliberative Process

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Wednesday, November 02, 2016 6:14 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: FinalSeafoodConsumptionRelease (4)SMB STM.doc

Here is the draft press release. It will likely go through many changes, but if you could review it with your comms folks and let us know if you have any edits and what quote you'd like for EPA, that would be terrific. If we could possibly get it back by Monday COB, I can show it to people here for a meeting we are having on Tuesday. I also will send forward a draft comms plan – again, same caveats. It hasn't cleared FDA yet but I'd really welcome your feedback. If we can indicate we are in sync with EPA, that would be very helpful.

Thanks for the info you provided. We will try to use your QAs and messaging and will provide you additional QAs and messaging on our end.

Hope this settles everyone down!

By the way, before you make an announcement, who besides your EPA Administrator needs to sign-off – Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

Thanks tons.

Sharon

To: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Tue 11/8/2016 8:11:16 PM
Subject: RE: Draft rollout for fish advice

I'm around tomorrow (unless incredibly hung over from tonight's results)

From: Christensen, Christina
Sent: Tuesday, November 08, 2016 2:29 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Draft rollout for fish advice

Ok, sounds like Cara is making edits to respond to Travis' points, and will send to us shortly to finish up (she has to leave by 3pm). However, I just got The Call from daycare and baby is running a fever so I need to leave shortly to get her. I am not sure my schedule for tomorrow, so can you take a look at what Cara has done, and finish responding to Travis' edits?

If you are not available, I may be able to do it first thing tomorrow.

From: Larimer, Lisa
Sent: Tuesday, November 08, 2016 1:55 PM
To: Christensen, Christina <Christensen.Christina@epa.gov>
Subject: RE: Draft rollout for fish advice

Ha ha ha ha, after Cara had me add all those attachments. . .

From: Christensen, Christina
Sent: Tuesday, November 08, 2016 1:54 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: FW: Draft rollout for fish advice

Travis' edits are attached.

I'm a little confused on the process here – not sure if Cara makes these edits, or if it comes back to us for editing? I'm checking with Cara, so maybe hold off making any changes for now.

From: Loop, Travis
Sent: Tuesday, November 08, 2016 11:29 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Dennis, Allison <Dennis.Allison@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
Subject: RE: Draft rollout for fish advice

Please see my comments and edits in the attached. Primarily I think we need to eliminate the "attachment" sections either because they propose a level of detail we don't need in the roll out doc or the content should be reflected elsewhere in the doc (and the press release should be standalone doc, not in roll out plan).

I didn't put this comment in the roll out but please add that Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

If you can revise this accordingly, I will take to OPA as a rough draft to get the issue on their plates and reach out to FDA comms. I think we will be most successful in working the comms from the top down.

Comments/edits to the chart and press release coming shortly…

Travis Loop

Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

From: Lalley, Cara
Sent: Monday, November 07, 2016 4:50 PM
To: Loop, Travis <Loop.Travis@epa.gov>
Cc: Dennis, Allison <Dennis.Allison@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
Subject: Draft rollout for fish advice

Ok- here's the first draft. Sorry there are still some pieces missing here and there. The faster you can review it, notify OPA and contact FDA Comms, the better....even if only so we can have a conference call before FDA gets too far through their approval chain. And then there's the election.

I did not bother to have Betsy S review this version. I figured she will be asked to review at least two future versions before the advice and press release actually go out (at least once after OW/OPA edits, and again after HHS review). There are so many things I need your input on at this stage, I figured it's best to keep the review group small for the first draft.

Thanks

From: Loop, Travis
Sent: Friday, November 04, 2016 9:47 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Dennis, Allison <Dennis.Allison@epa.gov>
Subject: RE: update: should get you draft rollout for fish advice COB Monday instead of Tuesday (eom)

Sounds good. Thanks.

Travis Loop

Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

From: Lalley, Cara
Sent: Thursday, November 03, 2016 6:29 PM
To: Loop, Travis <Loop.Travis@epa.gov>
Cc: Dennis, Allison <Dennis.Allison@epa.gov>
Subject: update: should get you draft rollout for fish advice COB Monday instead of Tuesday (eom)

Cara Lalley

Communications Coordinator

Office of Science & Technology

U.S. EPA Office of Water

(202)566-0372 (p)

(202)566-1140 (f)

To: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Tue 11/8/2016 6:55:26 PM
Subject: RE: Draft rollout for fish advice

Ha ha ha ha, after Cara had me add all those attachments. . .

From: Christensen, Christina
Sent: Tuesday, November 08, 2016 1:54 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
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Subject: RE: Draft rollout for fish advice

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Comments/edits to the chart and press release coming shortly…

Travis Loop

Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

From: Lalley, Cara
Sent: Monday, November 07, 2016 4:50 PM
To: Loop, Travis <Loop.Travis@epa.gov>
Cc: Dennis, Allison <Dennis.Allison@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
Subject: Draft rollout for fish advice

Ok- here's the first draft. Sorry there are still some pieces missing here and there. The faster you can review it, notify OPA and contact FDA Comms, the better….even if only so we can have a conference call before FDA gets too far through their approval chain. And then there's the election.

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Thanks

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To: Lalley, Cara <Lalley.Cara@epa.gov>
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Sounds good. Thanks.

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Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

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Cara Lalley

Communications Coordinator

Office of Science & Technology

U.S. EPA Office of Water

(202)566-0372 (p)

(202)566-1140 (f)

To: Lalley, Cara[Lalley.Cara@epa.gov]
Cc: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Tue 11/8/2016 6:40:03 PM
Subject: Q re: fish advice comm editing process

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, November 08, 2016 12:33 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Subject: RE: FinalSeafoodConsumptionRelease (4)SMB STM.doc

Lisa,

I assume they'll show you the edits before sending it to us? If so, can you discuss that with us before they send it to our comms folks? I'd like our workgroup to be comfortable with it before it goes to our media folks. Is that possible?

Thanks.

Sharon

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Monday, November 07, 2016 5:32 PM
To: Natanblut, Sharon
Cc: Dooren, Jennifer
Subject: RE: FinalSeafoodConsumptionRelease (4)SMB STM.doc

Sorry, the day got away from me. Here's what I know. The draft press release is working its way through our system; we'll provide an EPA quote; and your comms people can expect Travis Loop (I think) to contact them, probably later this week.

-Lisa

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]

Sent: Monday, November 07, 2016 11:50 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
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Ex. 5 - Deliberative Process

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Wednesday, November 02, 2016 6:14 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: FinalSeafoodConsumptionRelease (4)SMB STM.doc

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Hope this settles everyone down!

By the way, before you make an announcement, who besides your EPA Administrator needs to sign-off – Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Thanks tons.

Sharon

To: Lalley, Cara[Lalley.Cara@epa.gov]
Cc: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Mon 11/7/2016 6:10:43 PM
Subject: RE: drsft rollout plan for fish advice

Ex. 5 - Deliberative Process

I think that's all I need for FDA today – that it's working its way through our system; we'll provide a quote; and they can expect Travis (?) to contact them, possibly later this week. Does that sound right?

Do you want me to continue working on the rollout plan (e.g., the background attachment, etc.)? Not sure how you're going to handle version control.

From: Lalley, Cara
Sent: Monday, November 07, 2016 12:39 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>
Subject: RE: drsft rollout plan for fish advice

Ok- two different issues to be aware of:

1) For myself and the comm staff above me: when we make statements about Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

2) For SHPD and Betsy: I will provide OW with suggestions like below, but OW and OPA comm staff will decide on the quote in the press release and will provide FDA/HHS with whatever other edits to the press release they feel are warranted. They will do this as quickly as possible, but also at their own pace…..they will check with us to ensure their edits are factual, but there will likely be multiple rounds of review between high level comm folks at both agencies, and maybe also at the White House. All I can promise today is that I will get the draft

rollout up to Travis and Allison in OW. I will encourage them to review it quickly, get in touch with OPA and get in touch with FDA comms staff, but that's all we can do at the OST level. FDA comm staff are welcome to push on Travis Loop from their side—he will not be blindsided.

Thanks

From: Larimer, Lisa
Sent: Monday, November 07, 2016 11:58 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>
Subject: RE: drsft rollout plan for fish advice

FDA is requesting a **status check today** on the **press release** (one of the attachments to the rollout plan). They are hoping we will be gentle and not make a bunch of changes and supply an EPA quote. Betsy wanted something on **Ex. 5 - Deliberative Process** Here's are some options John came up with. I haven't had a chance to edit. You're welcome to take a crack at it yourself.

Betsy sez:

Ex. 5 - Deliberative Process

Alternative:

Ex. 5 - Deliberative Process

~John

From: Lalley, Cara
Sent: Monday, November 07, 2016 11:42 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>
Subject: RE: drsft rollout plan for fish advice

Got it- I also told Christina this morning that I don't think I'll get Betsy S to review this version before it goes to Travis. I'm hoping he can use it to quickly get his bearings and arrange a call with FDA comms folks. So, the next version of the rollout and press release are what I hope to provide Betsy for review. Otherwise, she'll look at it multiple times and probably lose her mind!

From: Larimer, Lisa
Sent: Monday, November 07, 2016 11:13 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>
Subject: RE: drsft rollout plan for fish advice

Just wanted you to know, Cara, that Sara and Betsy haven't seen this yet. Wanted to get your input before it goes up. Christina provided some comments that I think I haven't fully addressed yet.

From: Larimer, Lisa
Sent: Friday, November 04, 2016 5:55 PM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>
Subject: drsft rollout plan for fish advice

Hi Cara,

I did not really get to this today. Here is it, in draft form.

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Lalley, Cara[Lalley.Cara@epa.gov]
Cc: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Mon 11/7/2016 4:57:36 PM
Subject: RE: drsft rollout plan for fish advice

FDA is requesting a **status check today** on the **press release** (one of the attachments to the rollout plan). They are hoping we will be gentle and not make a bunch of changes and supply an EPA quote. Betsy wanted something on Ex. 5 - Deliberative Process
Here's are some options John came up with. I haven't had a chance to edit. You're welcome to take a crack at it yourself.

Betsy sez:

Ex. 5 - Deliberative Process

Alternative:

Ex. 5 - Deliberative Process

~John

From: Lalley, Cara
Sent: Monday, November 07, 2016 11:42 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>
Subject: RE: drsft rollout plan for fish advice

Got it- I also told Christina this morning that I don't think I'll get Betsy S to review this version before it goes to Travis. I'm hoping he can use it to quickly get his bearings and arrange a call with FDA comms folks. So, the next version of the rollout and press release are what I hope to provide Betsy for review. Otherwise, she'll look at it multiple times and probably lose her mind!

From: Larimer, Lisa
Sent: Monday, November 07, 2016 11:13 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>
Subject: RE: drsft rollout plan for fish advice

Just wanted you to know, Cara, that Sara and Betsy haven't seen this yet. Wanted to get your input before it goes up. Christina provided some comments that I think I haven't fully addressed yet.

From: Larimer, Lisa
Sent: Friday, November 04, 2016 5:55 PM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>
Subject: drsft rollout plan for fish advice

Hi Cara,

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Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Lalley, Cara[Lalley.Cara@epa.gov]
Cc: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Mon 11/7/2016 4:12:52 PM
Subject: RE: drsft rollout plan for fish advice

Just wanted you to know, Cara, that Sara and Betsy haven't seen this yet. Wanted to get your input before it goes up. Christina provided some comments that I think I haven't fully addressed yet.

From: Larimer, Lisa
Sent: Friday, November 04, 2016 5:55 PM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Christensen, Christina <Christensen.Christina@epa.gov>
Subject: drsft rollout plan for fish advice

Hi Cara,

I did not really get to this today. Here is it, in draft form.

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Mon 11/7/2016 2:41:17 PM
Subject: Fish advice materials
Peer Review Response-fish advice .11.3.2016 clean version.docx
2015-646_fish advice NOA. 10.31.2016 Final Version.docx
technical web page-fish advice 11.2.2016 (2).docx
Fish Advice Qs and As -11 3 2016 clean.docx
Summary_Table_of_Response_to_Public_comments 11.3.16 (3).docx
FISH_CHART_H_11.3.pdf
Fish Advice Peer Review Summary Report_9.28.16 (6).docx

You wanted to see these.

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Friday, November 04, 2016 7:38 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: FW: FYI Notification of FRDTS Record 2015-646 (Notice) Sent from CFSAN to RPMS

Hi Lisa,

Here are the current versions going to HHS.

Debbie

To: Lalley, Cara[Lalley.Cara@epa.gov]
Cc: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Fri 11/4/2016 9:54:36 PM
Subject: drsft rollout plan for fish advice
EPA-FDA Fish Consumption Advice 2016 Rollout-110416draft.docx

Hi Cara,

I did not really get to this today. Here is it, in draft form.

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Lalley, Cara[Lalley.Cara@epa.gov]
Cc: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Thur 11/3/2016 8:44:15 PM
Subject: draft press release for fish advice
FinalSeafoodConsumptionRelease (4)SMB STM.doc

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Wednesday, November 02, 2016 6:14 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: FinalSeafoodConsumptionRelease (4)SMB STM.doc

Here is the draft press release. It will likely go through many changes, but if you could review it with your comms folks and let us know if you have any edits and what quote you'd like for EPA, that would be terrific. If we could possibly get it back by Monday COB, I can show it to people here for a meeting we are having on Tuesday. I also will send forward a draft comms plan – again, same caveats. It hasn't cleared FDA yet but I'd really welcome your feedback. If we can indicate we are in sync with EPA, that would be very helpful.

To: Lalley, Cara[Lalley.Cara@epa.gov]
From: Larimer, Lisa
Sent: Thur 11/3/2016 8:43:18 PM
Subject: comm Qs

I'll send the draft press release for the fish advice. I imagine it will get quite worked over by comms folks on both sides, but if you have any comments, let me know and I'll pass them along to FDA.

Two questions to help me fill in their blanks.

(1) Does EPA have a phone number for questions like this one for FDA? Consumer Inquiries: 888-INFO-FDA

(2) FDA has a paragraph at the end describing who they are what they do. Do we usually put something like this on press releases? If not and if we'd like to add on, do we have a stock paragraph we could stick in there?

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Lalley, Cara[Lalley.Cara@epa.gov]; Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Thur 11/3/2016 7:05:36 PM
Subject: RE: Fish Advice and PROTRAC review?

Any word on the logo front yet?

From: Larimer, Lisa
Sent: Wednesday, November 02, 2016 5:01 PM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
Subject: RE: Fish Advice and PROTRAC review?

My question about the logo was whether we can use what's currently on the chart or if we have to use this one:

Here's the chart. I threw a draft watermark on it. And yes, please keep a close hold.

From: Lalley, Cara
Sent: Wednesday, November 02, 2016 3:44 PM
To: Christensen, Christina <Christensen.Christina@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Fish Advice and PROTRAC review?

Ugh. I was asking these same things to myself the other day. Strictly speaking, I think the answers are yes to PROTRAC and no to the seal (rather, we would use a simple form of the logo). But when other agencies are involved, some EPA guidance tends to fly out the window! That may be especially true for PROTRAC, if OW makes it clear that FDA is in the lead.

Is there any way you can send me a current draft of the chart so Travis can try to get final answers on these questions, with the understanding that it is JUST A DRAFT and should not be shared widely in EPA?

From: Christensen, Christina
Sent: Wednesday, November 02, 2016 3:35 PM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Fish Advice and PROTRAC review?

Is the fish advice chart/graphic something that will need PROTRAC review? Or has it already gone through PROTRAC review? I'm not very familiar with that process so wanted to check.

Also, Lisa and I were discussing the use of the EPA logo on the fish advice chart. We are trying to figure out the requirements for whether the flower can be used alone, or if text is required with the flower, what the preferred text should be (i.e., "EPA", "U.S. Environmental Protection Agency", "U.S. EPA" etc.). The online guidance is a little confusing. Cara, do you have a clearer answer this this question?

To: Loop, Travis[Loop.Travis@epa.gov]
From: Larimer, Lisa
Sent: Thur 11/3/2016 6:12:41 PM
Subject: RE: Question re: who else needs to agree before announcing fish advice

Thanks!

From: Loop, Travis
Sent: Thursday, November 03, 2016 2:08 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
Subject: RE: Question re: who else needs to agree before announcing fish advice

At the right time, our Office of Public Affairs will let Ex. 5 - Deliberative Process know about the announcement. They will weigh in on any messaging or timing issues. It's premature to do that now. Most important to get the roll out plan and media materials drafted and pushed up the chain.

Travis Loop

Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

From: Larimer, Lisa
Sent: Thursday, November 03, 2016 1:57 PM
To: Loop, Travis <Loop.Travis@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
Subject: Question re: who else needs to agree before announcing fish advice

Travis,

Sara Hisel-McCoy asked me to send this question along. It's about the fish consumption advice that we're hoping to release next month. I'm working with FDA on the rollout plan and press release as we speak. See the questions below – we think the answers are no, but wanted to be sure.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]

By the way, before you make an announcement, who besides your EPA Administrator needs to sign-off – **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

To: Loop, Travis[Loop.Travis@epa.gov]
Cc: Lalley, Cara[Lalley.Cara@epa.gov]; Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Thur 11/3/2016 5:56:59 PM
Subject: Question re: who else needs to agree before announcing fish advice

Travis,

Sara Hisel-McCoy asked me to send this question along. It's about the fish consumption advice that we're hoping to release next month. I'm working with FDA on the rollout plan and press release as we speak. See the questions below – we think the answers are no, but wanted to be sure.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]

By the way, before you make an announcement, who besides your EPA Administrator needs to sign-off – **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Dooren, Jennifer[Jennifer.Dooren@fda.hhs.gov]
From: Larimer, Lisa
Sent: Thur 11/3/2016 5:49:57 PM
Subject: RE: EPA logo, rollout plan, press release, other languages for fish advice, and OMB help

Your plan for the Spanish sounds good; do it! I'll look into how fast we could translate the chart and Q&A into other languages.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, November 03, 2016 11:33 AM
To: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: EPA logo, rollout plan, press release, other languages for fish advice, and OMB help

I think we should try to get the advice itself, including the QAs, translated into Spanish. I'm thinking we should get that done with the version we have and then pay for them to update it closer to release time. Lisa, does that work for you? Is this something EPA can do? We have folks we can reach out to if you'd prefer.

From: Dooren, Jennifer
Sent: Thursday, November 03, 2016 12:24 AM
To: Natanblut, Sharon; Larimer, Lisa
Subject: RE: EPA logo, rollout plan, press release, other languages for fish advice, and OMB help

Sure – I'm sure we can do Spanish PR and release it the same day as the English release but the translation wouldn't be done until right before this goes out so not sure about the 12/9 date (Gloria in OMA translates from the cleared English version) A QA sometimes follows but I'll make sure to raise this with our rollout coordinator

From: Natanblut, Sharon
Sent: Wednesday, November 02, 2016 6:21 PM
To: Larimer, Lisa

Cc: Dooren, Jennifer
Subject: RE: EPA logo, rollout plan, press release, other languages for fish advice, and OMB help

Regarding Spanish, I think it's a good idea and we should give it a try. Looping in Jen so she can add that to the comms plan.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, November 02, 2016 4:53 PM
To: Natanblut, Sharon
Subject: EPA logo, rollout plan, press release, other languages for fish advice, and OMB help

Hi Sharon,

A couple quick things:

(1) I'm trying to get a definitive answer, but we may need to change the EPA logo on the chart to

It can be in white on a dark background, like we have it now. I don't have access to the print quality files, but I can put your designer In touch with the right person. It looks like it's Belinda Blackman (202-564-7844, blackman.belinda@epa.gov), based on this link: https://www.epa.gov/stylebook/using-epa-seal-and-logo#pro (which has info on the different types of files available; I'm not sure what program your designer has been using to generate the charts).

(2) I'm getting crazy pressure for the rollout plan. I took the one we started working on jointly last year (at least I think it was jointly between the comms people) and started updating it. Before I get too far though, I wanted to check with you and make sure we're not concurrently duplicating efforts. So before I go any farther, here's what I've got (attached). Any chance you could look at it by Friday?

(3) Even if it's draft, can I get a version of the press release to plunk in the rollout plan? Thanks.

(4) My comms people are insisting we need to have this in other languages when we release in order to have a successful rollout. Since we have virtually no time, I'm pushing back that we can do other languages a little later. I'm probably going to lose on Spanish, though. Your thoughts on getting the press release, chart and Q&A into Spanish by 12/9?

(5) Given the short time OMB will have the materials, my managers are asking how we can help.

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Wed 11/2/2016 9:06:31 PM
Subject: FW: EPA logo, rollout plan, press release, other languages for fish advice, and OMB help
EPA-FDA Fish Consumption Advice 2016 Rollout.docx

Meant to cc you

From: Larimer, Lisa
Sent: Wednesday, November 02, 2016 4:53 PM
To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov) <Sharon.Natanblut@fda.hhs.gov>
Subject: EPA logo, rollout plan, press release, other languages for fish advice, and OMB help

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Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Lalley, Cara[Lalley.Cara@epa.gov]; Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Wed 11/2/2016 9:00:40 PM
Subject: RE: Fish Advice and PROTRAC review?
DRAFT_FISH_CHART_H_11.1.pdf

My question about the logo was whether we can use what's currently on the chart or if we have to use this one:

Here's the chart. I threw a draft watermark on it. And yes, please keep a close hold.

From: Lalley, Cara
Sent: Wednesday, November 02, 2016 3:44 PM
To: Christensen, Christina <Christensen.Christina@epa.gov>
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Subject: RE: Fish Advice and PROTRAC review?

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Is there any way you can send me a current draft of the chart so Travis can try to get final answers on these questions, with the understanding that it is JUST A DRAFT and should not be shared widely in EPA?

From: Christensen, Christina
Sent: Wednesday, November 02, 2016 3:35 PM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Fish Advice and PROTRAC review?

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To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 11/2/2016 8:53:25 PM
Subject: EPA logo, rollout plan, press release, other languages for fish advice, and OMB help
EPA-FDA Fish Consumption Advice 2016 Rollout.docx

Hi Sharon,

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Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Wed 11/2/2016 5:30:43 PM
Subject: RE: fish advice help

You noticed my head exploding, I see.

From: Christensen, Christina
Sent: Wednesday, November 02, 2016 11:13 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Subject: fish advice help

Hi there,

I'm available to help with the communications pieces in whatever way is most helpful to you (drafting, reviewing, brainstorming, etc) – just let me know. Sounds like Cara needs to see a draft (however draft it may be) by COB Tuesday.

FYI, I'll be on leave either Friday or Monday (probably Friday but TBD) but can help before/after that.

To: larimer Ex. 6 - Personal Privacy
From: Larimer, Lisa
Sent: Tue 11/1/2016 8:12:15 PM
Subject: rollout plan
EPA-FDA Fish Consumption Advice 2016 Rollout.docx

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Mon 10/31/2016 8:19:47 PM
Subject: RE: Action items from Joel's biweekly

Thanks

From: Barash, Shari
Sent: Monday, October 31, 2016 4:08 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Moore, Keara <Moore.Keara@epa.gov>
Subject: Fwd: Action items from Joel's biweekly

See fish advice and fish consumption survey guidance items.

Sent from my iPhone

Begin forwarded message:

From: "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Date: October 31, 2016 at 4:04:00 PM EDT
To: "Behl, Betsy" <Behl.Betsy@epa.gov>, "Flaherty, Colleen" <Flaherty.Colleen@epa.gov>, "Gallagher, Kathryn" <Gallagher.Kathryn@epa.gov>, "Strong, Jamie" <Strong.Jamie@epa.gov>, "Hisel-Mccoy, Sara" <Hisel-McCoy.Sara@epa.gov>, "Barash, Shari" <Barash.Shari@epa.gov>, "Buffo, Corey" <Buffo.Corey@epa.gov>, "Thomas, Dana" <Thomas.Dana@epa.gov>
Subject: Action items from Joel's biweekly

Plastics White Paper – need to send to Ellen to review after Betsy and I have reviewed. Need to then brief Joel and Ellen before it can go forward.

Fish Consumption Survey Guidance – need to brief Joel and Ellen on the comments received and our response

PFOA/PFOS comments on NJ Appendix – Joel needs to review before they are sent

HABs criteria – need to ensure all workgroup reps brief up to their managers and that Betsy Behl calls all their managers about a week after those briefings to ensure they are supportive of the criteria

EPA FDA fish advice – I will represent EPA, not any other higher level official

Flow Report – need a meeting with Jim and Ken on the flow report [Ex. 5 - Deliberative Process]

Ex. 5 - Deliberative Process

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Mon 10/31/2016 8:17:14 PM
Subject: RE: Comm strategy

If I interpreted the email chain correctly, Betsy Southerland will represent EPA again, not Joel or the Administrator.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, October 27, 2016 4:11 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Comm strategy

Thanks! That's very helpful.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, October 27, 2016 4:10 PM
To: Natanblut, Sharon
Subject: RE: Comm strategy

Betsy is ok with this approach. She will check in with Joel on Monday; Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, October 27, 2016 12:12 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Comm strategy

Absolutely.

We can expand on this (and we'll have to see what HHS wants to do), but I think that our goal is

to keep it simple and Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

You'll recall that last time, we had our Acting Commissioner Dr. Ostroff as the spokesperson for FDA and you had Betsy Southerland. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Do you have a sense of who would be the spokesperson this time? Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Is that along the lines that you were thinking? Do you have a sense of whether your leadership wants something more than that?

Thanks.

Sharon

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, October 27, 2016 11:50 AM
To: Natanblut, Sharon
Subject: Comm strategy

Morning Sharon,

Betsy has a meeting with Joel on Monday at 3 at which she can bring up the fish advice. It would be great if we had the communication strategy that she could hand over then, or at the very least, its status. Ex. 5 - Deliberative Process Think you could get me something by then?

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Lalley, Cara[Lalley.Cara@epa.gov]; Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Mon 10/31/2016 5:48:54 PM
Subject: Do you have a comm strategy for the EPA-FDA fish advice that I can update?

I have so many files related to the advice that I can't find the comm strategy. I thought we had done one. Do either of you have a version I can update?

Thanks!

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
Cc: Wathen, John[Wathen.John@epa.gov]; Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]
From: Larimer, Lisa
Sent: Thur 10/27/2016 6:46:59 PM
Subject: RE: latest Q and As and response to peer revdiew
Fish Advice Qs and As -10 26 16 LLL.docx

2-3 spacing fixes plus a small change to II.5. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

And I added page numbers. Got fed up every time my pages got out of order and I couldn't figure out which side/page came next.

Ex. 5 - Deliberative Process

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Wednesday, October 26, 2016 3:04 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: FW: latest Q and As and response to peer revdiew

Ex. 5 - Deliberative Process

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Smegal, Deborah
Sent: Wednesday, October 26, 2016 3:03 PM
To: 'Larimer, Lisa'
Cc: Jones, William
Subject: RE: latest Q and As and response to peer revdiew

If you make any changes, please use this version that includes John's edits.

debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, October 26, 2016 1:14 PM
To: Smegal, Deborah; Jones, William; Natanblut, Sharon; Wathen, John
Subject: RE: latest Q and As and response to peer revdiew

I'll look at these. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Wednesday, October 26, 2016 12:53 PM

To: Jones, William <William.Jones@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: latest Q and As and response to peer revdiew

Hi,

Attached are the latest versions (today's date) of the Qs and As and response to peer review (one change on page 8).

The Q and A's accepts Lisa's comments and here are responses to her questions:

Ex. 5 - Deliberative Process

What do others think? Do you have suggestions before we send this for clearance?

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Thur 10/27/2016 3:49:31 PM
Subject: Comm strategy

Morning Sharon,

Betsy has a meeting with Joel on Monday at 3 at which she can bring up the fish advice. It would be great if we had the communication strategy that she could hand over then, or at the very least, its status. He won't go to Gina until he knows what we're planning. Think you could get me something by then?

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Thur 10/27/2016 1:45:30 PM
Subject: RE: Update on Fish Advice?

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process I've asked FDA for the latest comm materials; I believe they last had the pen.

From: Christensen, Christina
Sent: Thursday, October 27, 2016 9:40 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Update on Fish Advice?

I've heard somewhat second (third?) hand that the EPA/FDA fish advice is now moving forward….any truth to this rumor?

To: Richard Dooley [Ex. 6 - Personal Privacy]
From: Larimer, Lisa
Sent: Wed 10/26/2016 3:49:30 PM
Subject: RE: The EPA-FDA fish advice is moving forward again!

groan

From: Richard Dooley [mailto:[Ex. 6 - Personal Privacy]
Sent: Wednesday, October 26, 2016 11:49 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: The EPA-FDA fish advice is moving forward again!

Yeaaaa! So, I guess your AM meeting today went……wait for it……..swimmingly?!

I'm here all day (except for the time where I'll be teleworking, of course).

Way to go, honey!

me

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, October 26, 2016 11:46 AM
To: rich [Ex. 6 - Personal Privacy]
Subject: FW: The EPA-FDA fish advice is moving forward again!

From: Larimer, Lisa
Sent: Wednesday, October 26, 2016 11:09 AM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>;

Behl, Betsy <Behl.Betsy@epa.gov>; Wood, Robert <Wood.Robert@epa.gov>; Lape, Jeff <lape.jeff@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Subject: The EPA-FDA fish advice is moving forward again!

Betsy, Joel, Ellen, and I met with Tom Burke and his ORD folks this morning. He was pleased with the results of the peer review that he requested, the caliber of the peer reviewers, and the changes the EPA-FDA workgroup has made to the advice. Tom and Joel agreed that we should target a December release (which is what FDA is striving for), and they will be talking to the Administrator about it. Woo hoo!

Here is the latest version of the advice chart, in case you're curious.

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Mon 10/24/2016 6:07:31 PM
Subject: RE: Briefing materials for Wed. 10:00: EPA-FDA Fish Advice

Sorry for the lack of clarity. I already sent these materials (plus the peer review charge questions as background for Joel) to Octavia, who sent them to Ann Campbell for Joel. So OW has them. I bcced you on the email to Tom Burke's scheduler in ORD. So ORD also has the materials now. As do you, as requested.

From: Barash, Shari
Sent: Monday, October 24, 2016 2:04 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Briefing materials for Wed. 10:00: EPA-FDA Fish Advice

Lisa,

I don't know this guy – does this mean you sent the materials forward to OW? Or are we still waiting to do that?

Shari

Shari Z. Barash

Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Larimer, Lisa
Sent: Monday, October 24, 2016 2:00 PM
To: Gentry, Nathan <Gentry.Nathan@epa.gov>
Subject: Briefing materials for Wed. 10:00: EPA-FDA Fish Advice

Hi Nathan,

Here are the briefing materials. Could you please add them to the meeting invitation?

Thanks!

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]; Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Mon 10/24/2016 6:05:29 PM
Subject: FYI: memo from Office of Children's Health Protection
OCHP memo 10122016.docx

Here's the internal memo from children's health. Hopefully I won't take heat for sharing it.

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Gentry, Nathan[Gentry.Nathan@epa.gov]
Bcc: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Mon 10/24/2016 5:59:48 PM
Subject: Briefing materials for Wed. 10:00: EPA-FDA Fish Advice
ORD briefing-fish advice-102616.docx
FISH_CHART_H_9.22.16.pdf

Hi Nathan,

Here are the briefing materials. Could you please add them to the meeting invitation?

Thanks!

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Conerly, Octavia[Conerly.Octavia@epa.gov]; Campbell, Ann[Campbell.Ann@epa.gov]
Cc: Gude, Karen[Gude.Karen@epa.gov]; Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Larimer, Lisa
Sent: Mon 10/24/2016 5:51:32 PM
Subject: RE: Seafood Advice Update

One small clarification: the charge questions are background information for Joel.

From: Conerly, Octavia
Sent: Monday, October 24, 2016 1:47 PM
To: Campbell, Ann <Campbell.Ann@epa.gov>
Cc: Gude, Karen <Gude.Karen@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Subject: RE: Seafood Advice Update

Hi Ann,

Attached are the briefing materials for the upcoming meeting.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4301T

Room 5233U

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Campbell, Ann

Sent: Monday, October 24, 2016 1:35 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Conerly, Octavia <Conerly.Octavia@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Seafood Advice Update

Thanks Betsy. Should I be looking for time to prebrief?

Also, I may have missed it, if so, please accept my apologies. But did we get cyanotoxins on the calendar yet? If not, would like to do that in the next 2 weeks. I think Ellen is in the office much of the time. Thanks.

From: Southerland, Elizabeth
Sent: Monday, October 24, 2016 11:07 AM
To: Campbell, Ann <Campbell.Ann@epa.gov>
Cc: Conerly, Octavia <Conerly.Octavia@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Seafood Advice Update

Sure thing! We will send the briefing materials this morning.

From: Campbell, Ann
Sent: Monday, October 24, 2016 9:34 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Conerly, Octavia <Conerly.Octavia@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>
Subject: RE: Seafood Advice Update

Betsy, we were able to add Joel to the briefing with Tom but since your biweekly has been a moving target, Joel will need something in advance to look at before Wednesday's meeting. Any chance you can get him materials/ an update today? He also has a few blocks of time tomorrow if we need to put 30 minutes on the calendar. Let me know.

Thanks,

Ann

From: Beauvais, Joel
Sent: Monday, October 17, 2016 3:52 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>
Subject: RE: Seafood Advice Update

OK, thanks, Ex. 5 - Deliberative Process I think we can defer the briefing until after Tom's (or we could do jointly?). Let's talk process at our biweekly so that I can send something back to Jeremy on this.

From: Southerland, Elizabeth
Sent: Monday, October 17, 2016 3:46 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>
Subject: RE: Seafood Advice Update

The peer reviewers agreed with what we did overall Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process We briefed the Children's Health Office last month, and Ex. 5 - Deliberative Process We couldn't get on Tom Burke's calendar until October 26 so were waiting to get his response before scheduling a briefing with you. Kacee Deener got all our information a month ago Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process I was going to brief you after we hear from Tom. If you want a briefing earlier, I can schedule one asap.

From: Beauvais, Joel
Sent: Monday, October 17, 2016 3:26 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>
Subject: FW: Seafood Advice Update

Hi, Betsy – Can we reconnect on this some time this week?

Joel

From: Sharp, Jeremy [mailto:Jeremy.Sharp@fda.hhs.gov]
Sent: Monday, October 17, 2016 3:23 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Subject: Seafood Advice Update

Hey Joel,

The ongoing saga of seafood advice continues and I wanted to check in with you on next steps and timelines. But first off, thanks very much for helping us get the peer review process done. Now we just have to nail down responding to the peer review.

I understand that the FDA/EPA work group have completed their review of the peer review comments, that they have incorporated the advice from the peer reviewers, and that the document is under review in EPA.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Given the positive work done by your team and ours we're hoping to get these documents cleared by the end of this month – does that seem possible to you? Any sense of how many hoops you all need to jump through on your end?

If it would be helpful, I'm happy to arrange for us to connect or for us to get our food team leadership together with key folks at your end – only if that is helpful of course.

Thanks again for getting us to this point,

Jeremy

Jeremy Sharp

Deputy Commissioner

Policy, Planning, Legislation, and Analysis

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, Maryland 20993

301-796-8770

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
From: Larimer, Lisa
Sent: Mon 10/24/2016 5:43:10 PM
Subject: Fish advice materials for Joel
FISH_CHART_H_9.22.16.pdf
ORD briefing-fish advice-102616.docx
Charge Questions-fish advice.docx

Octavia, I have attached the following documents.

Briefing materials:

- Briefing paper
- Fish advice chart

Background materials for Joel:

- Charge questions for peer reviewers

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
From: Larimer, Lisa
Sent: Mon 10/24/2016 3:47:31 PM
Subject: RE: Seafood Advice Update
Charge Questions-fish advice.docx
ORD briefing-fish advice-102616.docx
FISH_CHART_H_9.22.16.pdf

Octavia, I have attached the following documents. Let me know if Betsy thinks anything else would be helpful as background.

Briefing materials:

- □□□□□□□ Briefing paper
- □□□□□□□ Fish advice chart

Background materials for Joel:

- □□□□□□□ Charge questions for peer reviewers

From: Conerly, Octavia
Sent: Monday, October 24, 2016 10:28 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Seafood Advice Update

Lisa,

Send it to me so I can make sure Betsy is fine with it before we send it to Ann.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4301T

Room 5233U

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Larimer, Lisa
Sent: Monday, October 24, 2016 10:25 AM
To: Conerly, Octavia <Conerly.Octavia@epa.gov>
Subject: RE: Seafood Advice Update

Octavia, shall I send to you? Or directly to Ann and cc you?

From: Conerly, Octavia
Sent: Monday, October 24, 2016 9:48 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Subject: RE: Seafood Advice Update

Thanks Lisa.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4301T

Room 5233U

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Larimer, Lisa
Sent: Monday, October 24, 2016 9:47 AM
To: Conerly, Octavia <Conerly.Octavia@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Subject: RE: Seafood Advice Update

I can send the briefing materials later this morning.

From: Conerly, Octavia
Sent: Monday, October 24, 2016 9:44 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Subject: FW: Seafood Advice Update

Lisa,

Do we have something for Joel (some pre-brief material) to give to him before Wednesday's meeting with Tom Burke?

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4301T

Room 5233U

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Campbell, Ann
Sent: Monday, October 24, 2016 9:34 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Conerly, Octavia <Conerly.Octavia@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>
Subject: RE: Seafood Advice Update

Betsy, we were able to add Joel to the briefing with Tom but since your biweekly has been a moving target, Joel will need something in advance to look at before Wednesday's meeting. Any chance you can get him materials/ an update today? He also has a few blocks of time tomorrow if we need to put 30 minutes on the calendar. Let me know.

Thanks,

Ann

From: Beauvais, Joel
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To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>
Subject: RE: Seafood Advice Update

OK, thanks. **Ex. 5 - Deliberative Process** I think we can defer the briefing until after Tom's (or we could do jointly?). Let's talk process at our biweekly so that I can send something back to Jeremy on this.

From: Southerland, Elizabeth
Sent: Monday, October 17, 2016 3:46 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
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The peer reviewers agreed with what we did overall Ex. 5 - Deliberative Process

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Ex. 5 - Deliberative Process We briefed the Children's Health Office last month, and Ex. 5 - Deliberative Process We couldn't get on Tom Burke's calendar until October 26 so were waiting to get his response before scheduling a briefing with you. Kacee Deener got all our information a month ago Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process I was going to brief you after we hear from Tom. If you want a briefing earlier, I can schedule one asap.

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Cc: Campbell, Ann <Campbell.Ann@epa.gov>
Subject: FW: Seafood Advice Update

Hi, Betsy – Can we reconnect on this some time this week?

Joel

From: Sharp, Jeremy [mailto:Jeremy.Sharp@fda.hhs.gov]
Sent: Monday, October 17, 2016 3:23 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Subject: Seafood Advice Update

Hey Joel,

The ongoing saga of seafood advice continues and I wanted to check in with you on next steps and timelines. But first off, thanks very much for helping us get the peer review process done. Now we just have to nail down responding to the peer review.

I understand that the FDA/EPA work group have completed their review of the peer review comments, that they have incorporated the advice from the peer reviewers, and that the document is under review in EPA.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Given the positive work done by your team and ours we're hoping to get these documents cleared by the end of this month – does that seem possible to you? Any sense of how many hoops you all need to jump through on your end?

If it would be helpful, I'm happy to arrange for us to connect or for us to get our food team leadership together with key folks at your end – only if that is helpful of course.

Thanks again for getting us to this point,

Jeremy

Jeremy Sharp

Deputy Commissioner

Policy, Planning, Legislation, and Analysis

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, Maryland 20993

301-796-8770

FDA-EPA Fish Advice

Briefing for Dr. Thomas Burke, Assistant Administrator, Office of Research and Development and Joel Beauvais, Deputy Assistant Administrator, Office of Water
October 26, 2016

Key Findings of Peer Review

- Peer reviewers supported the use of mean mercury concentrations, mean body weight, and FDA's fish contamination data.

Changes to Fish Advice Since Briefings in 2015

Ex. 5 - Deliberative Process

s

Peer Review

- Purpose of review: Evaluate methods, data, and assumptions underlying fish advice
- Letter peer review with three reviewers
- Expertise we requested: Fish advisory practitioners, mercury risk assessment experts, dietary exposure analysts with seafood consumption expertise
    - Amy Kyle, Ph.D. Professor, Environmental Health Sciences, School of Public Health at University of California Berkeley. Research interests include policy for environmental public health protection including chemicals policies, children's environmental health, and contaminants in the food chain including persistent organic pollutants and metals.

- Emily Oken, M.D., MPH. Professor, Population Medicine at Harvard Medical School and Dept. of Nutrition at Harvard School of Public Health. Research projects included several that studied associations of maternal prenatal fish consumption, mercury, fatty acids, and infant development.
- Andrew Smith, Ph.D. State toxicologist and Director, Environmental & Occupational Health Programs, Maine Dept. of Health and Human Services. Projects include state's healthy fish eating guidelines.

- Majority of peer reviewers stated the advice was too restrictive for children.
  - Evidence on neurodevelopmental effects on children is lacking.

Status of Advice

- In order to complete HHS (and possible OMB) review and be released in December, need EPA and FDA concurrence by the end of October.

To: Wathen, John[Wathen.John@epa.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Mon 10/24/2016 2:20:20 PM
Subject: RE: Your review and comments kindly requested by 4:00, Tuesday, October 25, 2016 - Revised Fish Advice Documents

Oh yes, I also had thoughts on the Ex. 5 - Deliberative Process one. Looks like John commented.

From: Wathen, John
Sent: Monday, October 24, 2016 10:11 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Subject: RE: Your review and comments kindly requested by 4:00, Tuesday, October 25, 2016 - Revised Fish Advice Documents

I also think they are generally good, but have a few suggestions back.

~John

From: Larimer, Lisa
Sent: Monday, October 24, 2016 10:08 AM
To: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: Your review and comments kindly requested by 4:00, Tuesday, October 25, 2016 - Revised Fish Advice Documents

I think these look good except we might want to clarify this one a little more:

Ex. 5 - Deliberative Process

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Monday, October 24, 2016 7:33 AM
To: Jones, William <William.Jones@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: FW: Your review and comments kindly requested by 4:00, Tuesday, October 25, 2016 - Revised Fish Advice Documents

Hi,

We just received these editorial suggestions/comments on the Qs and A's from my office director, Conrad who just joined in September. I think many of these suggestions are helpful.

What do you think?

Debbie

From: Choiniere, Conrad
Sent: Friday, October 21, 2016 4:12 PM
To: Steadman, Marquita B
Cc: Smegal, Deborah
Subject: RE: Your review and comments kindly requested by 4:00, Tuesday, October 25, 2016 - Revised Fish Advice Documents

Given that I am coming in late on this issue, I focused my attention to the Qs and As. Please let me know if you want to discuss my comments.

Conrad

Conrad J. Choiniere, Ph.D.

Director, Office of Analytics and Outreach

Center for Food Safety and Nutrition

301.796.9228

From: Steadman, Marquita B
Sent: Thursday, October 20, 2016 4:45 PM
To: Bernard, Susan; Chao, Philip; Jones, William; Natanblut, Sharon; Mayne, Susan; Choiniere, Conrad; Balentine, Douglas; Hansen, Patricia A; Trumbo, Paula
Cc: Smegal, Deborah; Berry, Gerona; Hall-Wilson, Dashia; McKinnon, Robin; Osterman, Rachel
Subject: Your review and comments kindly requested by 4:00, Tuesday, October 25, 2016 - Revised Fish Advice Documents
Importance: High

Good afternoon –

The latest versions of the fish advice documents are attached. These documents have been staff level reviewed and cleared by OCC. FDA has requested EPA's clearance of the attached documents by the end of this month; **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Because the documents may still be revised, we cannot circulate them for "final" clearance. I am, however, asking that you review the attached documents and send any comments to me by 4:00 Tuesday, October 25, 2016. If there are significant changes to the documents, we will note them when we send the documents to you for final expedited review/clearance.

The following documents are attached:

1) NOA

2) Technical web page

3) Peer Review Response

4) Fish Advice Qs and As

5) Fish Advice Peer Review Summary Report

6) Summary Table of Responses to Public Comments

7) Fish Chart

Please let me know if you have any questions. Thank you.

Marquita

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Larimer, Lisa
Sent: Thur 11/19/2015 4:57:38 PM
Subject: RE: Updated & shortened options for fish advice

Never mind; Betsy saw it and forwarded.

From: Larimer, Lisa
Sent: Thursday, November 19, 2015 11:43 AM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Subject: FW: Updated & shortened options for fish advice
Importance: High

Betsy's out on sick leave today. Do you want to send this to Joel (or Heidi)? Or is it not worth it?

From: Larimer, Lisa
Sent: Thursday, November 19, 2015 11:07 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: Updated & shortened options for fish advice
Importance: High

Betsy-

It occurred to me this morning that since Joel has just recently gotten involved in the fish advice, he may not know that Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

I took the information I pulled together for last week's meeting with Joel and made some changes:

- □□□□□□□ boiled it down to one page of clear options
- □□□□□□□ added a few things I mentioned verbally at last week's meeting like Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

- [redacted] mentioned that state health departments sent comments and examples of their advisories Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process
- [redacted] added an option that we could Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process

I'm not sure if you'll have time to look at it and get it to Joel before his meeting at 2:00 today, but I thought it was worth a shot.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]
Bcc: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Larimer, Lisa
Sent: Tue 11/17/2015 9:53:07 PM
Subject: RE: question about comments
commenter table-updated Nov17.xlsx
FDA-2014-N-0595 2015-02-11 20-06-53.xlsx

Debbie et al-

Here is a list showing **221** comment submissions (see file called commenter table).

If you go sequentially, it skips numbers. After banging my head on this for several hours, I deduced:

•□□□□□□ At some point, comments started getting renumbered (without DRAFT in the title). I can't figure out the rhyme or reason behind it, but the Excel file with the longer names shows the renamed files as of February.

•□□□□□□ I highlighted comment numbers in my table that were missing and for which I could not find an associated renumbered comment. Then I started going through the docket and think I linked a few more (see comments in parentheses in the organization name column), but then the website quit working, so I gave up.

•□□□□□□ The table was generated based on what people entered electronically. For those that were showing up as anonymous but were representing an organization, at some point I had started filling in the name of the person who signed the letter. Sometimes no one signed the letter. I think I got them all.

•□□□□□□ Sometime a person's organization isn't showing, because again, it was based on what they typed in when they submitted it electronically. At some point last spring I started entering those (e.g., Harvard School of Public Health for Philippe Grandjean), but I remember I didn't get too far. Don't know if it matters, unless we want to be really complete in our list in the comment response document.

I don't know if there are more comments out there that should be counted. But at a minimum, we can show we received 221 separate submissions, not the 113 showing in the docket.

Sometimes you'll see where one person shows up multiple times. You'll have to go into the docket to see if these were duplicates, attachments, or someone submitting different comments on behalf of multiple organizations (as in the case of Mark Mitchell, which I've clarified in the table). If you assume back-to-back entries with the same name are either duplicates or attachments, there are 7 of those, reducing our **total number of submitters to 214**.

Once we verify how many we actually got (were there more? Do we count those that were received after the comment period ended?), we should update that total in the response to comments document, FR notice, and anywhere else we reference it.

Hope this helps!

-Lisa

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, November 12, 2015 2:59 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: FW: question about comments

Lisa/John,

Can you see below and help address this question?

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Smegal, Deborah
Sent: Thursday, November 12, 2015 2:46 PM
To: Jones, William
Subject: RE: question about comments

We think that the cover page for all the comments is counted as well, so this would about double the comments we found. I can check with John/Lisa unless you think this may be the explaination.

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Smegal, Deborah
Sent: Thursday, November 05, 2015 6:29 PM
To: Jones, William
Subject: question about comments

HI Bill,

My team is going through the public comments to pull relevant literature. We are using regulations.gov and only have found about 133 comments. Do you know how we arrived at the 222 figure earlier? Are there other comments on FDMS? If so, how can I access without a password? Thoughts?

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Christensen, Christina[Christensen.Christina@epa.gov]
Cc: McDonald, Ambria[McDonald.Ambria@epa.gov]
From: Larimer, Lisa
Sent: Mon 11/16/2015 7:11:11 PM
Subject: RE: Will we need updated communications materials on the fish advice?

I think it's premature, Ex. 5 - Deliberative Process

From: Christensen, Christina
Sent: Monday, November 16, 2015 1:03 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: McDonald, Ambria <McDonald.Ambria@epa.gov>
Subject: Will we need updated communications materials on the fish advice?

Lisa,

Cara has been asking Ambria and I whether or not any updated communications materials will be necessary for the fish advice. I think she specifically wants to know whether or not some updated Qs and As will be necessary in the immediate future, Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Please let us know so Cara can take necessary steps. Thanks!

Christina

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/27/2015 6:39:07 PM
Subject: RE: Thoughts

I think where we ended up yesterday was that we'd leave it as is, but I'll save these in case we do reopen it before finalizing. I think my preference is **Ex. 5 - Deliberative Process**

From: Wathen, John
Sent: Thursday, August 27, 2015 2:34 PM
To: Larimer, Lisa
Subject: Thoughts

Ex. 5 - Deliberative Process

~John

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 12:42 PM
To: Deborah Smegal (Deborah.smegal@fda.hhs.gov); Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov); Bill Jones (William.jones@fda.hhs.gov); Wathen, John
Subject: Summary of call with HHS & USDA on fish advice

If it's useful, here are my notes from the call yesterday. I captured a few things for us to keep in mind as we go along.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Larimer, Lisa
Sent: Wed 1/18/2017 7:51:37 PM
Subject: The EPA-FDA fish advice is on the street!

Hi Kacee,

I thought you'd be interested in hearing that our fish advice was released today. Thanks for your support. The pregnant women of America thank you!

Press release: https://www.epa.gov/newsreleases/epa-and-fda-issue-final-fish-consumption-advice-0

EPA's direct link to the EPA-FDA fish advice is https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish, although you can find it fairly easily from www.epa.gov/fishadvice.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]; Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/27/2015 4:42:12 PM
Subject: Summary of call with HHS & USDA on fish advice
Summary of 082615 meeting with HHS & USDA.docx

If it's useful, here are my notes from the call yesterday. I captured a few things for us to keep in mind as we go along.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

Summary of 8/26/15 call with HHS & USDA on new versions of fish advice and dietary guidelines

Participants
HHS/OASH: Rick Olson, Kellie Casavale
USDA: Collette Rahani
FDA: Sharon Natanblut, Bill Jones, Debbie Smegal
EPA: Lisa Larimer, John Wathen

Status of 2015 Dietary Guidelines
In development stage. Need technical and internal reviews. HHS hopes to start clearance process in mid-September and release by end of December 2015.

Feedback from HHS & USDA on fish advice

- Our new version is an important step forward and solves previous problems with the topic.
- It is sound, technically based advice that is transparent how we derived it and clear.
- Suggestions for us to consider:

Ex. 5 - Deliberative Process

Moving forward

- Ex. 5 - Deliberative Process
- HHS will keep FDA & EPA in the loop as they develop the content.
- Ex. 5 - Deliberative Process
- Both groups (fish advice and DGA) will keep each other informed re: exact timing.

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Fri 10/23/2015 3:06:52 AM
Subject: FW: EPA OIG investigation on contaminants in seafood

Forwarding Betsy's email

From: Southerland, Elizabeth
Sent: Thursday, October 22, 2015 4:16 PM
To: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Subject: RE: EPA OIG investigation on contaminants in seafood

The meetings we have had with the OIG have all focused on EPA's work on the state fish consumption advisories, not on the joint FDA EPA advice. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process We are still waiting for EPA senior level reviews of the current version.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, October 22, 2015 1:26 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: FW: EPA OIG investigation on contaminants in seafood

Hi there,

Just heard about this and was hoping we could find a time to discuss.

Thanks.

Sharon

From: Natanblut, Sharon
Sent: Thursday, October 22, 2015 1:25 PM
To: Sharp, Jeremy; Kux, Leslie
Cc: Boon, Caitlin; McKinnon, Robin; Cristinzio, Dayle; Pillsbury, Laura; Saben, Alyson L; Bernard, Susan;

Mayne, Susan; Harper, Kristina; Taylor, Michael R
Subject: RE: EPA OIG investigation on contaminants in seafood

FYI

From: Sonya Lunder [mailto:sonya@ewg.org]
Sent: Thursday, October 22, 2015 12:09 PM
To: Natanblut, Sharon
Subject: EPA OIG investigation on contaminants in seafood

Sharon,

Here is the EPA OIG notice about its investigation into contaminant warnings by EPA's Office of Water. As I also mentioned today, EWG is planning to formally ask EPA and FDA to hold of on finalizing the draft seafood advice while this investigation is pending. We believe the draft advice is not health protective, as detailed in our public comments to FDA. We have provided OIG with model advice from state governments that is more comprehensive and nuanced, as a model for the federal agencies to employ when advising pregnant women and parents.

Thanks for forwarding this information to the scientists in charge of mercury issues. I would be eager to speak with them about the Agency's plans to incorporate public comments and update the draft advice.

- Sonya

Sonya Lunder, MPH

Environmental Working Group

Washington DC 20009

Sonya@ewg.org

202/939-9129

To: Martin, Jeanette[Martin.Jeanette@epa.gov]
From: Larimer, Lisa
Sent: Thur 11/12/2015 10:39:42 PM
Subject: Can you please forward me the fish advice invitation (Fri @1)?

So in case the time or place changes, I'll know.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Frey, Sharon[Frey.Sharon@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/27/2015 4:12:14 PM
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

Oh really? Didn't know that. Thanks!

From: Frey, Sharon
Sent: Thursday, August 27, 2015 12:11 PM
To: Larimer, Lisa
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

Yes, but I don't know who's covering staff meeting tomorrow from our end so it's good to make sure that everything's in the talking point. Betsy doesn't usually go.

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 12:08 PM
To: Frey, Sharon
Subject: FW: Please send Friday staff meeting items by 11:00 am tomorrow

We've briefed Ken on this recently, so it shouldn't be Martian to him.

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 12:06 PM
To: Frey, Sharon
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

No. Dietary Guidelines for Americans

From: Frey, Sharon
Sent: Thursday, August 27, 2015 12:05 PM
To: Larimer, Lisa
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

DGA means Dietary Guidelines Advice?

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 11:01 AM
To: Frey, Sharon
Subject: FW: Please send Friday staff meeting items by 11:00 am tomorrow

Apparently I just sent this to myself

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 11:00 AM
To: Larimer, Lisa
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

Slight revision at the end – see red addition and strikeout

EPA-FDA fish advice

•□□□□□□ The fish advice team called phone call or the name? I think a phone call but thought I'd check anywaythe Dietary Guidelines group in HHS and USDA on Wednesday. The DGA group felt Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

•□□□□□□ Status of 2015 Dietary Guidelines: in development stage. HHS still needs to determine Ex. 5 - Deliberative Process Will keep us in the loop. HHS hopes to start clearance process for the Dietary Guidelines **(header of bullet is dietary guidelines)** or Fish Advice or both? in mid-September and release by end of December 2015.

•□□□□□□ Both groups (fish advice and DGA) felt it is important that Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process so we ~~will submit~~ have submitted the Administrator meeting request to finish EPA clearance~~, unless you have concerns~~. The advice has made it out of FDA and is in HHS clearance process.

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 9:43 AM
To: Frey, Sharon
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

From: Frey, Sharon
Sent: Thursday, August 27, 2015 9:04 AM
To: Larimer, Lisa
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

See questions below in different color

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

From: Larimer, Lisa
Sent: Wednesday, August 26, 2015 3:06 PM
To: Frey, Sharon; Barash, Shari; Buffo, Corey; Fabiano, Claudia; Keating, Jim; Martinez, Menchu; Vlcan, Manjali; Wathen, John; Wilcut, Lars
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

EPA-FDA fish advice

•□□□□□□ The fish advice team called phone call or the name? I think a phone call but thought I'd check anywaythe Dietary Guidelines group in HHS and USDA on Wednesday. The DGA group felt Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

•□□□□□□ Status of 2015 Dietary Guidelines: in development stage. HHS still needs to Ex. 5 - Deliberative Process Will keep us in the loop. HHS hopes to start clearance process for the Dietary Guidelines (header of bullet is dietary guidelines) or Fish Advice or both? in mid-September and release by end of December 2015.

•□□□□□□ Both groups (fish advice and DGA) felt Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process so we will submit the Administrator meeting request to finish EPA clearance, unless you have concerns. The advice has made it out of FDA and is in HHS clearance process.

From: Frey, Sharon
Sent: Wednesday, August 26, 2015 2:43 PM
To: Barash, Shari; Buffo, Corey; Fabiano, Claudia; Keating, Jim; Larimer, Lisa; Martinez, Menchu; Vlcan, Manjali; Wathen, John; Wilcut, Lars
Subject: Please send Friday staff meeting items by 11:00 am tomorrow

If I receive nothing, I'll assume you have nothing.

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

To: Barash, Shari[Barash.Shari@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 11/12/2015 10:20:16 PM
Subject: FW: Additional information on fish advice in prep for Fri 1:00 with ORD
Fish advice-info for Joel Beauvais.docx

The final product

From: Larimer, Lisa
Sent: Thursday, November 12, 2015 3:52 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Subject: Additional information on fish advice in prep for Fri 1:00 with ORD

Joel-

Betsy asked me to send this. Please let us know if you have any comments or questions so we can revise this before the 1 PM meeting with ORD.

Thanks!

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/27/2015 4:11:54 PM
Subject: RE: Summary of call w/ HHS & USDA on fish advice & dietary guidelines

Thanks! I'd like to think that conciseness? concision? is something I'm good at.

From: Wathen, John
Sent: Thursday, August 27, 2015 11:46 AM
To: Larimer, Lisa
Cc: Barash, Shari
Subject: RE: Summary of call w/ HHS & USDA on fish advice & dietary guidelines

Nice concise summary, Lisa.

~John

From: Larimer, Lisa
Sent: Wednesday, August 26, 2015 1:05 PM
To: Hisel-Mccoy, Sara
Cc: Barash, Shari; Wathen, John
Subject: Summary of call w/ HHS & USDA on fish advice & dietary guidelines

Sara-

On Wednesday, Lisa and John and their FDA counterparts on the fish advice had a call with HHS and USDA on the 2015 Dietary Guidelines. It went well and there are no apparent hurdles, so they will submit the Administrator meeting request unless you have concerns.

Status of 2015 Dietary Guidelines

•□□□□□□ In development stage. HHS will determine **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

•□□□□□□ HHS hopes to start clearance process in mid-September and **release by end of December 2015**.

Feedback on fish advice

Ex. 5 - Deliberative Process

Moving forward

•□□□□□□ HHS will keep FDA & EPA in the loop as they develop the DGA content.

•□□□□□□ Both groups (fish advice and DGA) felt it is important that Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process Both groups will keep each other informed re: exact timing.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Jones, William[William.Jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Larimer, Lisa
Sent: Fri 12/18/2015 8:59:36 PM
Subject: RE: Congressional re Fish Advice

We heard about it; our Administrator is on the cc list…

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Friday, December 18, 2015 2:54 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Congressional re Fish Advice

FYI: we are supposed to pass responsive language up our chain by 12/28.

William R. Jones, Ph.D.

Deputy Director, Office of Food Safety

Center for Food Safety and Applied Nutrition, USFDA

5100 Paint Branch Parkway

College Park, MD 20740

To: Ex. 6 - Personal Privacy
From: Larimer, Lisa
Sent: Wed 1/18/2017 6:22:43 PM
Subject: EPA-FDA fish advice has been released!

Hi Joel,

I thought you'd be interested in hearing that our fish advice did indeed go out. Thanks for your support. The pregnant women of America thank you!

Press release: https://www.epa.gov/newsreleases/epa-and-fda-issue-final-fish-consumption-advice-0

EPA's direct link to the EPA-FDA fish advice is https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish, although you can find it fairly easily from www.epa.gov/fishadvice.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Frey, Sharon[Frey.Sharon@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/27/2015 4:07:53 PM
Subject: FW: Please send Friday staff meeting items by 11:00 am tomorrow

We've briefed Ken on this recently, so it shouldn't be Martian to him.

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 12:06 PM
To: Frey, Sharon
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

No. Dietary Guidelines for Americans

From: Frey, Sharon
Sent: Thursday, August 27, 2015 12:05 PM
To: Larimer, Lisa
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

DGA means Dietary Guidelines Advice?

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 11:01 AM
To: Frey, Sharon
Subject: FW: Please send Friday staff meeting items by 11:00 am tomorrow

Apparently I just sent this to myself

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 11:00 AM
To: Larimer, Lisa
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

Slight revision at the end – see red addition and strikeout

EPA-FDA fish advice

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Ex. 5 - Deliberative Process so we ~~will submit~~ have submitted the Administrator meeting request to finish EPA clearance~~, unless you have concerns~~. The advice has made it out of FDA and is in HHS clearance process.

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 9:43 AM
To: Frey, Sharon
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

From: Frey, Sharon
Sent: Thursday, August 27, 2015 9:04 AM
To: Larimer, Lisa
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

See questions below in different color

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

From: Larimer, Lisa
Sent: Wednesday, August 26, 2015 3:06 PM
To: Frey, Sharon; Barash, Shari; Buffo, Corey; Fabiano, Claudia; Keating, Jim; Martinez, Menchu; Vlcan, Manjali; Wathen, John; Wilcut, Lars
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

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Subject: Please send Friday staff meeting items by 11:00 am tomorrow

If I receive nothing, I'll assume you have nothing.

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 10/22/2015 5:56:22 PM
Subject: RE: EPA OIG investigation on contaminants in seafood

I'm calling Sharon now.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, October 22, 2015 1:26 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: FW: EPA OIG investigation on contaminants in seafood

Hi there,

Just heard about this and was hoping we could find a time to discuss.

Thanks.

Sharon

From: Natanblut, Sharon
Sent: Thursday, October 22, 2015 1:25 PM
To: Sharp, Jeremy; Kux, Leslie
Cc: Boon, Caitlin; McKinnon, Robin; Cristinzio, Dayle; Pillsbury, Laura; Saben, Alyson L; Bernard, Susan; Mayne, Susan; Harper, Kristina; Taylor, Michael R
Subject: RE: EPA OIG investigation on contaminants in seafood

FYI

From: Sonya Lunder [mailto:sonya@ewg.org]
Sent: Thursday, October 22, 2015 12:09 PM
To: Natanblut, Sharon
Subject: EPA OIG investigation on contaminants in seafood

Sharon,

Here is the EPA OIG notice about its investigation into contaminant warnings by EPA's Office of Water. As I also mentioned today, EWG is planning to formally ask EPA and FDA to hold of on finalizing the draft seafood advice while this investigation is pending. We believe the draft advice is not health protective, as detailed in our public comments to FDA. We have provided OIG with model advice from state governments that is more comprehensive and nuanced, as a model for the federal agencies to employ when advising pregnant women and parents.

Thanks for forwarding this information to the scientists in charge of mercury issues. I would be eager to speak with them about the Agency's plans to incorporate public comments and update the draft advice.

- Sonya

Sonya Lunder, MPH

Environmental Working Group

Washington DC 20009

Sonya@ewg.org

202/939-9129

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/27/2015 4:07:00 PM
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

We've briefed Ken on this recently, so it shouldn't be Martian to him.

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 12:06 PM
To: Frey, Sharon
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

No. Dietary Guidelines for Americans

From: Frey, Sharon
Sent: Thursday, August 27, 2015 12:05 PM
To: Larimer, Lisa
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

DGA means Dietary Guidelines Advice?

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 11:01 AM
To: Frey, Sharon
Subject: FW: Please send Friday staff meeting items by 11:00 am tomorrow

Apparently I just sent this to myself

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 11:00 AM
To: Larimer, Lisa
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EPA-FDA fish advice

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Office of Science and Technology

Office of Water

202-566-1480

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Subject: Please send Friday staff meeting items by 11:00 am tomorrow

If I receive nothing, I'll assume you have nothing.

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Fri 12/18/2015 8:50:50 PM
Subject: RE: Congressional re Fish Advice

Sara sent this to us yesterday in a separate thread, so they know about it. Gina was cced.

From: Wathen, John
Sent: Friday, December 18, 2015 2:58 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Fw: Congressional re Fish Advice

I'll let you pass this up the chain. This is getting interesting.

~John

From: Jones, William <William.Jones@fda.hhs.gov>
Sent: Friday, December 18, 2015 2:53 PM
To: Larimer, Lisa; Wathen, John
Cc: Natanblut, Sharon; Smegal, Deborah
Subject: Congressional re Fish Advice

FYI: we are supposed to pass responsive language up our chain by 12/28.

William R. Jones, Ph.D.

Deputy Director, Office of Food Safety

Center for Food Safety and Applied Nutrition, USFDA

5100 Paint Branch Parkway

College Park, MD 20740

To: Kearney, Renee[Kearney.Renee@epa.gov]; Lalley, Cara[Lalley.Cara@epa.gov]
From: Larimer, Lisa
Sent: Wed 1/18/2017 3:00:48 PM
Subject: RE: Are you all set? Have everything you need? - use this test page to review

No time for coffee! I have a meeting. ☹

From: Kearney, Renee
Sent: Wednesday, January 18, 2017 10:00 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>
Subject: RE: Are you all set? Have everything you need? - use this test page to review

No problem – great teamwork!!!!

Enjoy your coffee!!!

All the tweeks have been completed now I will work on moving that banner.

Renee Kearney, Webmaster

202-564-8076 (Office)

202-281-0176 (Work Cell)

Smile to brighten somebody's day

Help to touch somebody's heart

From: Larimer, Lisa
Sent: Wednesday, January 18, 2017 9:57 AM

To: Lalley, Cara <Lalley.Cara@epa.gov>; Kearney, Renee <Kearney.Renee@epa.gov>
Subject: RE: Are you all set? Have everything you need? - use this test page to review

Thanks for all your hard work, you two! Now I can possibly relax for a moment with a cup of coffee!

From: Lalley, Cara
Sent: Wednesday, January 18, 2017 9:44 AM
To: Kearney, Renee <Kearney.Renee@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Are you all set? Have everything you need? - use this test page to review

Woohoo- nice job, ladies!

From: Kearney, Renee
Sent: Wednesday, January 18, 2017 9:41 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Are you all set? Have everything you need? - use this test page to review

done

Renee Kearney, Webmaster

202-564-8076 (Office)

202-281-0176 (Work Cell)

Smile to brighten somebody's day

Help to touch somebody's heart

From: Lalley, Cara
Sent: Wednesday, January 18, 2017 9:37 AM
To: Kearney, Renee <Kearney.Renee@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Are you all set? Have everything you need? - use this test page to review

Here's our press release: https://www.epa.gov/newsreleases/epa-and-fda-issue-final-fish-consumption-advice-0

From: Kearney, Renee
Sent: Wednesday, January 18, 2017 9:19 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>
Subject: RE: Are you all set? Have everything you need? - use this test page to review

Press release link

I'm not seeing on EPA's press release page

Should we use FDA's link?

Renee Kearney, Webmaster

202-564-8076 (Office)

202-281-0176 (Work Cell)

Smile to brighten somebody's day

Help to touch somebody's heart

From: Larimer, Lisa
Sent: Wednesday, January 18, 2017 9:16 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Kearney, Renee <Kearney.Renee@epa.gov>

Subject: RE: Are you all set? Have everything you need? - use this test page to review

Oh! I remembered! Since it's hot off the presses, can we make the fish advice the first banner box? Unless I'm wrong and box 1 isn't the first one that loads when you look at the page.

From: Larimer, Lisa
Sent: Wednesday, January 18, 2017 9:14 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Kearney, Renee <Kearney.Renee@epa.gov>
Subject: RE: Are you all set? Have everything you need? - use this test page to review

Yes. I agree; it's looking good. Internal links are working.

Wondering a few things:

1) On the document page for the advice (https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish-documents) should we have the Q&As there too? Alternatively, we you currently click on the link for Q&A, it goes to FDA where their pdf version has the two bundled together (http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM537120.pdf) I'm thinking it would be good to have a version where the chart and Q&A are combined. Sorry for the stream of consciousness typing here, but Cara, what do you think about having that combined pdf on our document page?

2) Darn it! I lost my other thoughts. Rushed in and haven't had coffee yet.

From: Lalley, Cara
Sent: Wednesday, January 18, 2017 9:07 AM
To: Kearney, Renee <Kearney.Renee@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Are you all set? Have everything you need? - use this test page to review

Looking good! On the Fish-Tech homepage, in the green box that says Choose Fish and Shellfish Wisely, should we add a NEW icon next to the third bullet to the EPA-FDA advice?

From: Kearney, Renee
Sent: Wednesday, January 18, 2017 8:58 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Are you all set? Have everything you need? - use this test page to review

Pages live – please review

Need press release link and fr link

https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish

https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish-documents

https://www.epa.gov/fish-tech/epa-fda-fish-advice-technical-information

https://www.epa.gov/choose-fish-and-shellfish-wisely/should-i-be-concerned-about-eating-fish-and-shellfish

https://www.epa.gov/fish-tech

https://www.epa.gov/choose-fish-and-shellfish-wisely/fish-and-shellfish-advisories-and-safe-eating-guidelines

https://www.epa.gov/choose-fish-and-shellfish-wisely

Renee Kearney, Webmaster

202-564-8076 (Office)

202-281-0176 (Work Cell)

Smile to brighten somebody's day

Help to touch somebody's heart

From: Lalley, Cara
Sent: Wednesday, January 18, 2017 8:53 AM
To: Kearney, Renee <Kearney.Renee@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Are you all set? Have everything you need? - use this test page to review

As Renee makes pages live, we will need to review them for any hiccups.

From: Kearney, Renee
Sent: Wednesday, January 18, 2017 6:18 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>
Subject: RE: Are you all set? Have everything you need? - use this test page to review

---

Renee Kearney, Webmaster

202-564-8076 (Office)

202-281-0176 (Work Cell)

Smile to brighten somebody's day

Help to touch somebody's heart

From: Larimer, Lisa
Sent: Tuesday, January 17, 2017 4:37 PM
To: Kearney, Renee <Kearney.Renee@epa.gov>
Subject: Are you all set? Have everything you need?

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Frey, Sharon[Frey.Sharon@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/27/2015 4:06:08 PM
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

No. Dietary Guidelines for Americans

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Sent: Thursday, August 27, 2015 12:05 PM
To: Larimer, Lisa
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

DGA means Dietary Guidelines Advice?

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

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Sharon Frey

Office of Science and Technology

Office of Water

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If I receive nothing, I'll assume you have nothing.

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

To: Barash, Shari[Barash.Shari@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Fri 12/18/2015 5:12:53 PM
Subject: does this look good?

Aiming for detailed but not too much….

Note for 1/5/15 meeting with FDA:

OST will work with schedulers for Jeremy Sharpe, Tom Burke, and Joel Beauvais to move the Jan. 5 meeting. The workgroup hopes to have Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process by the week of Jan. 18 and will try to schedule a meeting for that week.

Status of EPA's requests:

On Monday Dec. 14, OST staff traveled to FDA Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

In response to the 3 requests given on paper in the meeting with FDA on 12/3:

1. **Messaging:** Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

2. **Data:** Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

3. **Peer review:** Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

- Both FDA and EPA have peer review contracts in place. FDA could get a review started faster than OST, Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process The process of selecting the potential peer reviewers could be started before the holidays, while we are still working on the charge questions.

- The workgroup would like to Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

- For the charge questions, the workgroup will solicit input from Tom Burke's group.

FDA and EPA will need to jointly agree on the charge questions.

In response to the 3 additional areas Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

1. **Messaging – commercial fishermen:** Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

2. **Children's portion size:** Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

3. **Ensuring 3 servings will meet the RfD:** Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Wed 12/16/2015 1:37:03 PM
Subject: Fw: Rescheduling the FDA-EPA meeting on fish advice

Shari-

Process question for you. What's the best way to get Joel and Tom B's schedulers to work with FDA's?

From: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Sent: Tuesday, December 15, 2015 5:03 PM
To: Larimer, Lisa
Subject: RE: Rescheduling the FDA-EPA meeting on fish advice

I think our schedulers would need to work that out – suggest you offer several dates/times.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, December 15, 2015 4:02 PM
To: Natanblut, Sharon
Subject: Rescheduling the FDA-EPA meeting on fish advice

Hi Sharon,

The invitation I saw on Joel's calendar was from him to a bunch of FDA people (no EPA people), but I was wondering if your folks sent him a date they were all available and then he sent the invite. If that's the case, it would help if you could let me know when FDA people are available later in January (assuming we need more time than Jan 5 to pull things together), then I can get Joel's people to change the meeting request.

Thanks!

Lisa Larimer, P.E.

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 11/12/2015 3:03:32 PM
Subject: FW: Ex. 5 - Deliberative Process
Statistics_Fish in Good Category_Fish Advice_1192015 (3).xlsx

FYI

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Tuesday, November 10, 2015 5:35 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Ex. 5 - Deliberative Process

Hi,

We did some comparison of Ex. 5 - Deliberative Process too in the attached spreadsheet.. We have identified some issues with this paper as well that I will forward. I am just getting prepared for comments related to the use of F Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

See attached spreadsheet, Tab #1 for calculations

We did some trend analysis to address the comment that some suggested our data is outdated. For trend analysis, a linear regression was performed with raw EPA/FDA data using SigmaPlot 12. Data from ALL years was included. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

See attached spreadsheet, Tabs #5-13 for calculations.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, November 10, 2015 5:00 PM
To: Smegal, Deborah
Subject: FW: Ex. 5 - Deliberative Process

Hi Debbie,

Yesterday and today have been a whirlwind. Got your message and email. Thanks for Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

I hear you're looking at Ex. 5 - Deliberative Process We did too, and here's a quick analysis I did Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process I'll attach.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

It's available at

Ex. 5 - Deliberative Process

I have a hard copy. I could scan it Thursday and send it if you can't access it somehow. Gotta run!

To: Shari Barash[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Thur 10/1/2015 2:02:01 PM
Subject: briefing and chart
FDA-EPA Fish Advice for ORD.pptx
Fish Advice Qs and As-8 24 15 clean with comment box for NIH and placeholder for diagram.docx

Chart is in the Q&A

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 10/15/2015 8:15:13 PM
Subject: RE: last time to review--need feedback ASAP today
Fish Advice Qs and As-10 15 15-LL.docx

The technical appendix looked fine. We had a few things in the Q&A and fixed some formatting, deleted a duplicate Q&A, etc. The response to HHS is your internal document, so for the sake of expediency, we won't review.

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, October 15, 2015 2:00 PM
To: Natanblut, Sharon; Jones, William; Larimer, Lisa; Wathen, John
Subject: last time to review--need feedback ASAP today

Any last comments before I send forward?

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Larimer, Lisa
Sent: Tue 11/10/2015 4:14:45 PM
Subject: RE: Do you know over what time period OMB had the fish advice for review?

Sharon N came through. Dec 2013-June 2014

From: Wathen, John
Sent: Tuesday, November 10, 2015 8:02 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Bigler, Jeff <Bigler.Jeff@epa.gov>
Subject: RE: Do you know over what time period OMB had the fish advice for review?

Haven't the foggiest.

~John

From: Larimer, Lisa
Sent: Sunday, November 08, 2015 11:43 PM
To: Wathen, John <Wathen.John@epa.gov>; Bigler, Jeff <Bigler.Jeff@epa.gov>
Subject: Do you know over what time period OMB had the fish advice for review?

I'm pulling together a timeline and have been asked to include the OMB review, but I have no clue when that was. Can either of you dig that up? I'll probably need it before Monday afternoon.

Thanks!

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Hisel-Mccoy, Sara[Hisel-McCoy.Sara@epa.gov]
Cc: Shari Barash[Barash.Shari@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Wed 8/26/2015 5:04:58 PM
Subject: Summary of call w/ HHS & USDA on fish advice & dietary guidelines

Sara-

On Wednesday, Lisa and John and their FDA counterparts on the fish advice had a call with HHS and USDA on the 2015 Dietary Guidelines. It went well and there are no apparent hurdles, so they will submit the Administrator meeting request unless you have concerns.

Status of 2015 Dietary Guidelines

- In development stage. HHS will Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process
- HHS hopes to start clearance process in mid-September and **release by end of December 2015**.

Feedback on fish advice

- Our new version is more helpful than past advice and solves previous problems with the topic.
- It is sound, technically based advice that is transparent how we derived it and clear.

Moving forward

- HHS will keep FDA & EPA in the loop as they develop the DGA content.
- Both groups (fish advice and DGA) felt Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process Both groups will keep each other informed re: exact timing.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 10/15/2015 1:29:13 PM
Subject: FW: Revised advice -- please review and see if this works for you guys -- we are trying to return to HHS. Thx
FISH_CHART_H_10.13 (2).pdf - Adobe Acrobat Pro.pdf

Hi John,

I'm finally able to concentrate on this and will get back with Sharon. I was wondering what you thought of these potential changes:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Thoughts?

Oh, and did you have a **Ex. 5 - Deliberative Process**

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, October 15, 2015 8:50 AM
To: Larimer, Lisa; Wathen, John
Cc: Smegal, Deborah; Jones, William
Subject: Revised advice -- please review and see if this works for you guys -- we are trying to return to HHS. Thx
Importance: High

To: Loop, Travis[Loop.Travis@epa.gov]; Lalley, Cara[Lalley.Cara@epa.gov]
From: Larimer, Lisa
Sent: Tue 8/25/2015 3:40:47 PM
Subject: Communications for FDA-EPA fish advice

Hi Travis and Cara,

I sent your names to my FDA contact and told her you should be connected with their communications people. And by the way, you're also on the invite list for the Administrator briefing.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Frey, Sharon[Frey.Sharon@epa.gov]
Cc: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Wed 10/14/2015 8:55:26 PM
Subject: RE: Any Friday staff meeting agenda items? Please send to me by 11:00 am tomorrow.

I may try to pull together some compelling points for Ken when he meets with the Admin on the FDA-EPA fish advice. Not sure if I can get it done by 11 though.

From: Frey, Sharon
Sent: Wednesday, October 14, 2015 3:03 PM
To: Barash, Shari; Buffo, Corey; Fabiano, Claudia; Keating, Jim; Larimer, Lisa; Martinez, Menchu; Vlcan, Manjali; Wathen, John; Wilcut, Lars
Subject: Any Friday staff meeting agenda items? Please send to me by 11:00 am tomorrow.

If I receive nothing, I'll assume you have nothing.

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Mon 11/9/2015 5:24:54 PM
Subject: RE: Senate Briefing on Seafood Advisory

I can talk to you about what went down. Feel free to give me a call whenever, or we can chat tomorrow when you're back in the office.

From: Wathen, John
Sent: Monday, November 09, 2015 11:42 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Subject: Re: Senate Briefing on Seafood Advisory

Betsy-

My concern is that we're breaking the window without **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

~John

From: Southerland, Elizabeth
Sent: Monday, November 9, 2015 7:25 AM
To: Borum, Denis
Cc: Wathen, John; Larimer, Lisa; Hisel-Mccoy, Sara
Subject: Re: Senate Briefing on Seafood Advisory

Joel has contacted the FDA political and is arranging a call with him either late today or tomorrow morning.

Sent from my iPhone

On Nov 6, 2015, at 5:34 PM, Borum, Denis <Borum.Denis@epa.gov> wrote:

Barring a change of heart **Ex. 5 - Deliberative Process** I will try to talk with my AA prior to the Monday afternoon with Joel. Thank you for the heads-up.

Sent from my iPhone

On Nov 6, 2015, at 4:24 PM, Southerland, Elizabeth <Southerland.Elizabeth@epa.gov> wrote:

> Joel is making the call Ken never got to make to FDA. Joel will give me instructions on how to proceed on Monday. Stay tuned.
>
> Sent from my iPhone
>
> On Nov 6, 2015, at 4:18 PM, Wathen, John <Wathen.John@epa.gov> wrote:
>
> > I am in the office and available Nov 16.
> >
> > ~John

From: Larimer, Lisa
Sent: Friday, November 6, 2015 12:06 PM
To: Southerland, Elizabeth; Wathen, John
Cc: Borum, Denis; Hisel-Mccoy, Sara
Subject: RE: Senate Briefing on Seafood Advisory

Hi Betsy,

Sara and I can be available between 1 and 4:30 on Monday, November 16 if you want us there. John is out until Tuesday, but his calendar looks like he could make himself available too.

From: Goitom, Mahlet [mailto:Mahlet.Goitom@fda.hhs.gov]
Sent: Friday, November 06, 2015 11:11 AM

To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Stuckey, Carla <Carla.Stuckey@fda.hhs.gov>; Thomas, Clayton (OS) <Clayton.Thomas@hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>
Subject: Senate Briefing on Seafood Advisory

Dear Colleagues,

The Senate Agriculture Appropriations Subcommittee reached out to FDA requesting a briefing to discuss the status of the pending Seafood Advisory for Pregnant Women. FDA leadership thought it would be helpful to have EPA attend the briefing. We plan to hold a pre-call to prepare for the briefing, and **Ex. 5 - Deliberative Process** We would like to know if you all are available for an in-person briefing with the Committee on Monday, November 16th between 1 and 3pm or 4-430pm.

We look forward to hearing back.

Thank you,

Mahlet Goitom

Congressional Affairs Specialist / Office of Budget / FDA

8455 Colesville Road

Silver Spring, MD 20993-0002

Phone: 301-796-6832

BB: 301-512-7357

Email: Mahlet.Goitom@fda.hhs.gov

To: Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]; Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/20/2015 9:10:36 PM
Subject: Newest technical appendix
technical web page-fish advice-08 20 15 EPA edits 2.docx

I looked it over and it seems ok. Fixed some formatting, double spacing between words, etc. Use this one! (after you accept changes, of course – same with the Q&A)

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Shari Barash[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Wed 9/30/2015 7:56:38 PM
Subject: presentation for ORD
FDA-EPA Fish Advice for ORD.pptx

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Fleisig, Erica[Fleisig.Erica@epa.gov]
From: Larimer, Lisa
Sent: Wed 10/14/2015 12:22:36 AM
Subject: RE: OST Week-in-Review: September 21-25

Aw, shucks! Thanks, Erica!

From: Fleisig, Erica
Sent: Monday, October 12, 2015 3:26 PM
To: Larimer, Lisa
Subject: Fw: OST Week-in-Review: September 21-25

Nice work lady! I'm sure the awesome hairdo you were rocking that day helped wow them, in addition to your mad briefing skillz

---

From: Conerly, Octavia on behalf of Southerland, Elizabeth
Sent: Monday, September 28, 2015 4:48 PM
To: OST-EVERYONE
Subject: OST Week-in-Review: September 21-25

OST Week-in-Review: September 21 - 25

EPA/FDA Joint Fish Advice: Big kudos to Lisa Larimer on her briefing to the Deputy Administrator, ORD and OCHP on the Joint EPA-FDA Fish Advice on September 22nd. Lisa delivered an excellent briefing. Lisa, John Wathen, and Samantha Fontenelle handled several tough questions from ORD's AA and have put in extra effort last week and over the weekend to be responsive. **Ex. 5 - Deliberative Process** FDA is briefing the HHS Secretary this Wednesday.

New Hire Announcements

Melissa (Mimi) Soo-Hoo:

Mimi joins the Regional Branch in SHPD. She comes to OST from OWOW, where she was an ORISE Participant providing assistance in the National Aquatic Resource Survey and related products. Mimi has a Masters of Environmental Science and Management from UC Santa Barbara and did her undergraduate work at UCLA. Welcome Mimi!

Julianne (Julie) McLaughlin:

Julie has been an ORISE fellow in SHPD for the last 2 years, providing science and policy research support to the Water Quality Standards Program, and is now a full time employee in the Regional Branch in SHPD. Julianne received her PHD from the Department of Environmental Engineering Sciences from the University of Florida and did her undergraduate work at the College of Charleston. Welcome Julie!

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

To: Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]; Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/20/2015 8:57:25 PM
Subject: Newest Q&A document
Fish Advice Qs and As-8 20 15_EPA edits with links.docx

I looked over Debbie's changes and she caught everything. I added some hyperlinks that got lost in the version control mess. Use this one!

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: McDonald, Ambria[McDonald.Ambria@epa.gov]
From: Larimer, Lisa
Sent: Wed 9/30/2015 6:45:55 PM
Subject: FW: Adding to your "do today" list
Summary of All Public Comments on Advice 20150407 - Final.docx

From: Larimer, Lisa
Sent: Wednesday, September 30, 2015 1:38 PM
To: Wathen, John; Fontenelle, Samantha
Subject: Adding to your "do today" list

In preparation for the meeting with ORD tomorrow morning, we need a few more things (in addition to what was brought up this morning):

Sam – can you find the link to our pamphlet on how to properly clean fish to reduce contaminants and print out copies? Maybe 10.

John – please resend list of groups/people presenting at RCAC.

One of you (flip a coin) – look through our more detail comment document (I'll try to find and attach) to see if Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Larimer, Lisa
Location: 3319A WJC East
Importance: Normal
Subject: Accepted: FW: FDA Fish Advice
Start Date/Time: Mon 11/9/2015 4:30:00 PM
End Date/Time: Mon 11/9/2015 5:00:00 PM

To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]; Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]; Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/20/2015 8:45:48 PM
Subject: Clean version of response to comments
Summary Table of Response to Public comments 8 20 15 clean.docx

I'm out tomorrow, so contact John with any concerns. Thanks!

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 12/15/2015 4:23:43 PM
Subject: RE: Fish advice meeting

Of course

-----Original Message-----
From: Wathen, John
Sent: Tuesday, December 15, 2015 11:22 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: FW: Fish advice meeting

Lisa-

I think we will need to provide **Ex. 5 - Deliberative Process** **Ex. 5 - Deliberative Process** Thoughts?

~John

-----Original Message-----
From: Southerland, Elizabeth
Sent: Tuesday, December 15, 2015 9:52 AM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Cc: Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: Fish advice meeting

Great news! We need to develop a schedule for how long we think we need at the staff level to conclude our discussions. Then Jeremy Sharp should schedule a meeting with Joel and Tom Burke because he will know at that point if **Ex. 5 - Deliberative Process**

-----Original Message-----
From: Hisel-Mccoy, Sara
Sent: Tuesday, December 15, 2015 9:40 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Re: Fish advice meeting

Betsy- Happily, lisa john and team met with FDA yesterday afternoon and they made some progress. Lisa will getting back to you with a summary a little later today.

Sara Hisel-McCoy
Standards and Health Protection Division
202 566-1649

> On Dec 15, 2015, at 9:17 AM, Southerland, Elizabeth <Southerland.Elizabeth@epa.gov> wrote:
>
> Will do. We will work with the FDA staff to reschedule after we have had a chance to talk through Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process
>
> -----Original Message-----
> From: Beauvais, Joel
> Sent: Tuesday, December 15, 2015 9:12 AM
> To: Penman, Crystal <Penman.Crystal@epa.gov>; Southerland, Elizabeth

<Southerland.Elizabeth@epa.gov>
> Subject: Fish advice meeting
>
> Hi it looks like there's a meeting on Fish Advice with FDA on my calendar for 1/5 and it has Jeremy Sharp on it. I think next step is just for Betsy and company to talk to FDA counterparts without me and Jeremy so can you guys connect on this and adjust the calendar accordingly? Thanks in advance.
>
> Joel

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Fri 10/9/2015 3:03:31 AM
Subject: RE: HHS responses for fish advice

Hi,

I was hoping to get through this before I left town, but it's not happening tonight. Still pulling together family's stuff for trip, and the taxi is picking us up at 5:45 in the morning, so it's not going to happen tomorrow either. Our meeting with the DA got cancelled, so we have some time. This isn't getting cleared before next week. ☹

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, October 08, 2015 5:33 PM
To: Larimer, Lisa; Wathen, John
Subject: FW: HHS responses for fish advice

Hi,

Here are the latest versions of the documents going through our FDA clearance.

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Smegal, Deborah
Sent: Thursday, October 08, 2015 5:14 PM
To: Mayne, Susan; Natanblut, Sharon; Jones, William
Cc: Boon, Caitlin; Trumbo, Paula; McKinnon, Robin; Bernard, Susan; Elkin, Ted; Steadman, Marquita B; Flannery, Brenna; Kim, Grace (Grace.Kim@fda.hhs.gov); Dennis, Sherri
Subject: HHS responses for fish advice

Hi,

Attached please find all the latest documents to include:

(1) Response to HHS comments in a table format

(2) Qs and As with track changes

(3) Technical document with track changes

(4) Response to Public comment document with track changes

This incorporates input from Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process These documents are all consistent, so if there are changes to one, you may need to update the others.

I named all the files with 10.8.15 for version control.

I think Marquita has the cover memo that will accompany the responses.

I would like to express my sincere appreciation to Brenna Flannery and Grace Kim for their assistance in QA and helping us to pulling this together in such a short time frame.

Most importantly have a great weekend!! I plan to be off tomorrow but can be reached on my personal cell at Ex. 6 - Personal Privacy and might check email periodically.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Mon 11/9/2015 3:52:02 PM
Subject: RE: When did OMB have the fish advice for review?

Find out any dates yet? My meeting got scheduled for 11:30 this morning.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, November 09, 2015 9:32 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: When did OMB have the fish advice for review?

Thanks! I'll see what I can find out right now.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Monday, November 09, 2015 9:31 AM
To: Natanblut, Sharon
Subject: RE: When did OMB have the fish advice for review?

Yes, sorry, that was late last night and I wasn't clear. I meant for the draft advice, yes.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, November 09, 2015 7:53 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Re: When did OMB have the fish advice for review?

Do you mean how long it took for the draft advice? I can check on that for you this morning.

Sent from my BlackBerry 10 smartphone.

From: Larimer, Lisa

Sent: Sunday, November 8, 2015 11:45 PM

To: Natanblut, Sharon

Subject: When did OMB have the fish advice for review?

Hi Sharon,

I'm trying to pull a timeline together for our new assistant administrator of water, and I've been asked to include the OMB review. Do you know over what time period that was? Both Jeff and John are out, and I probably need the answer by Monday lunchtime.

Thanks for any assistance you can provide,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 9/30/2015 5:14:09 PM
Subject: sign-offs on fish advice

Can I get a list of who within HHS (including FDA I assume) has cleared the advice so far and what level/position they are? Would really like to have this before 10:30 tomorrow.

-Lisa

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Larimer, Lisa
Sent: Thur 8/20/2015 7:43:09 PM
Subject: RE: Revised response to comments
Summary Table of Response to Public comments 8 20 15 tracked changes.docx

I haven't tackled the formatting yet, but you can share this with Rachel. The biggest change was at the end. (dropping response to refer to a Q&A)

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, August 20, 2015 3:03 PM
To: Larimer, Lisa
Subject: RE: Revised FR notice

Excellent!!

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, August 20, 2015 3:01 PM
To: Smegal, Deborah; Natanblut, Sharon; Jones, William; Wathen, John; Bigler, Jeff
Subject: RE: Revised FR notice

OK. I'm back, so I should be able to get an unreformatted version of the comments table to you shortly for Rachel to see.

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, August 20, 2015 2:55 PM
To: Larimer, Lisa; Natanblut, Sharon; Jones, William; Wathen, John; Bigler, Jeff
Subject: RE: Revised FR notice

Thanks Lisa,

Rachel has cleared this FR notice, the Q and A's and the technical appendix (after we tweek some language in a footnote).

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, August 20, 2015 12:19 PM
To: Natanblut, Sharon; Smegal, Deborah; Jones, William; Wathen, John; Bigler, Jeff
Subject: Revised FR notice

In tracked changes. (I took the bold move of accepting changes where there was an extra space between words and making the hyperlinked formatting consistent!) I did not change the "per week" phrases where they referred to previous advice (2004, 2014 draft) or DGA because those

probably did say per week.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Fri 10/9/2015 2:57:55 AM
Subject: RE: **Ex. 5 - Deliberative Process**

When I was talking to Debbie earlier today she seemed to think **Ex. 5 - Deliberative Process** Ex. 5 - Deliberative Process I knew the DGAs had to get out in December but was curious if they seemed to be on a faster track.

Ex. 5 - Deliberative Process

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, October 08, 2015 6:54 PM
To: Larimer, Lisa; Smegal, Deborah; Jones, William; Wathen, John
Subject: RE: **Ex. 5 - Deliberative Process**

Why do you ask? I don't think the timeframe for when they have to go out has changed but I thought it was December.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, October 08, 2015 5:45 PM
To: Smegal, Deborah; Natanblut, Sharon; Jones, William; Wathen, John
Subject: RE: **Ex. 5 - Deliberative Process**

Do we think there's a chance the DGAs will go out before December?

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, October 08, 2015 11:33 AM
To: Natanblut, Sharon; Jones, William; Larimer, Lisa; Wathen, John
Subject: FW: **Ex. 5 - Deliberative Process**

Hi Guys,

Just wanted you to see more details about the comparison we did between the 2010 and 2015 deliberative DGAs. I asked Brenna to do a cross walk and below is her email to me. We updated the graph, plan to cite DGA 2015 (rather than DGA 2010) pending approval.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Flannery, Brenna
Sent: Wednesday, October 07, 2015 11:09 AM
To: Smegal, Deborah
Subject: Ex. 5 - Deliberative Process

Hi Debbie – Please see what I found below. Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

-

Where fish advice references Dietary Guidelines 2010:

Technical Appendix

Ex. 5 - Deliberative Process

Q's and A's

Ex. 5 - Deliberative Process

DGAs 2015 Wording:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Brenna Flannery, PhD

Toxicologist, Contaminant Assessment Branch

Division of Risk and Decision Analysis/OAO/CFSAN

Harvey W. Wiley Building (CPK1), Rm 2A-037

5100 Paint Branch Parkway

College Park, MD 20740

Brenna.flannery@fda.hhs.gov

Ph: 240-402-3081

To: McRae, Evelyn[McRae.Evelyn@epa.gov]
Cc: Barash, Shari[Barash.Shari@epa.gov]; Martinez, Menchu[martinez.menchu-c@epa.gov]
From: Larimer, Lisa
Sent: Thur 12/10/2015 10:03:51 PM
Subject: RE: Items for weekly OD notes

Fish advice : Lisa, John and Sam are traveling to FDA this afternoon Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: McRae, Evelyn
Sent: Thursday, December 10, 2015 4:29 PM
To: Buffo, Corey <Buffo.Corey@epa.gov>; Keating, Jim <Keating.Jim@epa.gov>; Fabiano, Claudia <Fabiano.Claudia@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Martinez, Menchu <martinez.menchu-c@epa.gov>; Wilcut, Lars <Wilcut.Lars@epa.gov>; Vlcan, Manjali <Vlcan.Manjali@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: McRae, Evelyn <McRae.Evelyn@epa.gov>
Subject: Items for weekly OD notes

Please send items for the Monday OD weekly staff meeting by 12/11/2015 1:00pm.

Thanks,

Evelyn M.

202.566.1018

From: Brundage, Jennifer
Sent: Thursday, December 10, 2015 4:25 PM
To: McRae, Evelyn <McRae.Evelyn@epa.gov>
Cc: Fabiano, Claudia <Fabiano.Claudia@epa.gov>
Subject: request for inclusion in OD notes

Hi Evelyn,

Could you please add the following to next week's OD notes?

- ME proposed rule Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Thanks,

Jenn

Jennifer Brundage

Regional Branch

Standards and Health Protection Division| Office of Science and Technology |Office of Water

U.S. Environmental Protection Agency

202-566-1265

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
From: Larimer, Lisa
Sent: Mon 9/21/2015 5:16:14 PM
Subject: RE: Briefing for FDA-EPA fish advice on 9/22 with DA

I figured it was something like that. Thanks for all your hard work!

From: Conerly, Octavia
Sent: Monday, September 21, 2015 12:55 PM
To: Larimer, Lisa
Subject: RE: Briefing for FDA-EPA fish advice on 9/22 with DA

Lisa,

The briefing went to Ken as soon as Betsy approved it. On Friday I guess there was some confusion as to whether or not it had gone to the Administrator. It is OW's responsibility to send the materials on to the Administrator's office after Ken's approval.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Larimer, Lisa
Sent: Monday, September 21, 2015 12:50 PM

To: Conerly, Octavia
Subject: RE: Briefing for FDA-EPA fish advice on 9/22 with DA

Hi Octavia,

What happened? I came back today to find my email blew up on Friday (when I was out) with people requesting a copy of the briefing and saw an email from Betsy this morning sending the briefing to Matt. I figured since you'd been hounding me for it, it would have gone up on Wednesday. Or did it, and people just didn't realize it? ☺

-Lisa

From: Larimer, Lisa
Sent: Wednesday, September 16, 2015 2:31 PM
To: Conerly, Octavia
Cc: Hisel-Mccoy, Sara
Subject: Briefing for FDA-EPA fish advice on 9/22 with DA

Octavia-

Sara has reviewed the briefing. I am also including the files for the horizontal and vertical versions of the charts – they are easier to read than in the briefing. I believe Betsy only forwarded one version up to Ken for his briefing; you may want to check with her on that for this time.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Frey, Sharon[Frey.Sharon@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/20/2015 6:22:53 PM
Subject: Blurb for Friday AA meeting

EPA-FDA fish advice

•□□□□□□□ The materials (chart, Q&As, response to comments, etc.) have finally cleared FDA and are entering HHS' clearance process today (Friday).

•□□□□□□□ We are holding off submitting the meeting request to brief the Administrator until we and FDA meet with the HHS and USDA group that is revising the Dietary Guidelines for Americans. We want to make sure there are no issues. We are meeting with them next week (Tues. or Wed.). We envision 3 possible outcomes:

Ex. 5 - Deliberative Process

•□□□□□□□ After we know which direction the DGA group is leaning, which should be next week – **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process - we will schedule the Administrator's briefing.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Larimer, Lisa
Importance: Normal
Subject: Meeting Forward Notification: FDA/EPA fish advice meeting
Start Date/Time: Thur 12/10/2015 10:00:00 PM
End Date/Time: Thur 12/10/2015 10:30:00 PM

Your meeting was forwarded

Larimer, Lisa has forwarded your meeting request to additional people.

Meeting
FDA/EPA fish advice meeting

Meeting Time
Monday, December 14, 2015 2:00 PM - Monday, December 14, 2015 5:00 PM

Recipients
Fontenelle, Samantha

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/20/2015 6:01:46 PM
Subject: RE: Draft note for Friday AA meeting

Thanks!

From: Wathen, John
Sent: Thursday, August 20, 2015 1:56 PM
To: Larimer, Lisa
Subject: RE: Draft note for Friday AA meeting

Couple of suggested changes.

~John

From: Larimer, Lisa
Sent: Thursday, August 20, 2015 1:49 PM
To: Wathen, John
Subject: Draft note for Friday AA meeting

John - Did I capture this correctly? I didn't take notes, but I noticed you did.

EPA-FDA fish advice

•□□□□□□□ The materials (chart, Q&As, response to comments, etc.) have finally cleared FDA and are entering HHS' clearance process today (Friday).

•□□□□□□□ We are holding off submitting the meeting request to brief the Administrator until we and FDA meet with the HHS and USDA group that is revising the Dietary Guidelines for Americans. We want to make sure there are no issues. We are meeting with them next week (Tues. or Wed.). We envision 3 possible outcomes:

1. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

•□□□□□□ After we know which direction the DGA group is leaning, which should be next week – Ex. 5 - Deliberative Process - we will schedule the Administrator's briefing.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 10/8/2015 6:30:49 PM
Subject: RE: Ex. 5 - Deliberative Process suggestions
FISH_CHART-mockup-option 1.pdf
FISH_CHART-mockup-option 1.docx

I put together rough mock-ups in preparation for the meeting with the Deputy Administrator this afternoon. Most folks here are leaning toward the option we hammered out together on Monday (attached in Word and pdf). I don't think Debbie ever sent out the language for Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process so I apologize if I didn't get it exactly as we discussed. I know I changed Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, October 08, 2015 2:10 PM
To: Smegal, Deborah; Jones, William; Larimer, Lisa; Wathen, John
Subject: RE: Ex. 5 - Deliberative Process suggestions

Thanks Deb for moving everything forward so well. Really appreciate it.

Lisa or John, I would like to go to the designer with one or both options regarding Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process Can you provide any insights as to whether there is support for one or the other option? Can you send me please exactly the language you are proposing for the two options? I flagged this issue here with Mike Taylor and Susan Mayne and they want to see how it looks before weighing in – **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Sharon

From: Smegal, Deborah
Sent: Thursday, October 08, 2015 2:05 PM
To: Jones, William; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Subject: Ex. 5 - Deliberative Process suggestions

Hi guys,

I would like to get all the documents I sent yesterday finished today if possible. I plan to be off tomorrow. Lisa/John do you want to add to the Qs and A's from Sharon/Bill? Or the response to comments doc?

Here an update to the technical appendix Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

For the Q and A response here is a proposed response:

Ex. 5 - Deliberative Process

Here is suggested updated language to eh Q and A. (I'm waiting on Paula to confirm Sharon's addition—but I believe the language is supported in the primary studies Hibblen and Daniels that we sent her)

Ex. 5 - Deliberative Process

Thoughts? Let me know as soon as you can.

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

This is easier for consumers to understand – can we say this?

From: Larimer, Lisa
Location: CFSAN CP Room 2A023
Importance: Normal
Subject: Accepted: FDA/EPA fish advice meeting
Start Date/Time: Mon 12/14/2015 7:00:00 PM
End Date/Time: Mon 12/14/2015 10:00:00 PM

From: Larimer, Lisa
Location: DCRoomWest6105AAssateague/DC-EPA-West-OST
Importance: Normal
Subject: Accepted: Update on Fish Advice
Start Date/Time: Mon 9/21/2015 5:15:00 PM
End Date/Time: Mon 9/21/2015 5:45:00 PM

To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]; Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]; Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/20/2015 4:19:19 PM
Subject: Revised FR notice
FRDTS#2015-646-draft FR notice-fish consumption advice revised version 8 20 2015.docx

In tracked changes. (I took the bold move of accepting changes where there was an extra space between words and making the hyperlinked formatting consistent!) I did not change the "per week" phrases where they referred to previous advice (2004, 2014 draft) or DGA because those probably did say per week.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Barash, Shari[Barash.Shari@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Martinez, Menchu[martinez.menchu-c@epa.gov]
From: Larimer, Lisa
Sent: Thur 10/8/2015 5:52:28 PM
Subject: pdf of option 1
FISH_CHART-mockup-option 1.pdf

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 12/10/2015 3:46:55 PM
Subject: RE: Should we try to meet next Monday?

Great! Debbie, please reserve a room. I think starting at 2:00 will be fine.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Wednesday, December 09, 2015 7:32 PM
To: Jones, William <William.Jones@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Cc: Wathen, John <Wathen.John@epa.gov>
Subject: RE: Should we try to meet next Monday?

Sure! Count me in. I'm a glutton.

From: Jones, William
Sent: Wednesday, December 09, 2015 6:13 PM
To: Natanblut, Sharon; Larimer, Lisa; Smegal, Deborah
Cc: Wathen, John
Subject: Re: Should we try to meet next Monday?

Yes - would be good - I could do from 2:00 on, and if necessary could reschedule what I currently have at 1:00.

From: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Date: December 9, 2015 at 5:52:05 PM EST
To: Larimer, Lisa <Larimer.Lisa@epa.gov>, Jones, William <William.Jones@fda.hhs.gov>, Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Cc: Wathen, John <Wathen.John@epa.gov>
Subject: Re: Should we try to meet next Monday?

Sounds like a good idea to me. I am free Monday afternoon and could get a room.

Debbie

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Larimer, Lisa

Sent: Wednesday, December 9, 2015 5:46 PM

To: Natanblut, Sharon; Jones, William; Smegal, Deborah

Cc: Wathen, John

Subject: Should we try to meet next Monday?

Ex. 5 - Deliberative Process let's meet to figure out our next steps. It would be great if we could get together before John and I disappear for the holidays (starting Dec 18). John and I are free all of Monday afternoon and we're willing to travel out your way. Are you all available?

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Larimer, Lisa
Location: See notes section for call-in info
Importance: Normal
Subject: CALL: FDA-EPA meeting to consolidate edits
Start Date/Time: Thur 8/20/2015 1:30:00 PM
End Date/Time: Thur 8/20/2015 4:00:00 PM
List of commenters.docx

1- Ex. 6 - Personal Privacy
Conference code: Ex. 6 - Personal Privacy
Participant code: Ex. 6 - Personal Privacy

Topics

1. Changes & suggested edits to fish advice documents
   a. From FDA OCC (in documents Debbie is sending)
   b. From EPA OGC (e.g., Ex. 5 - Deliberative Process)
   c. Other issues raised (e.g., Ex. 5 - Deliberative Process
   Ex. 5 - Deliberative Process

Identifying key commenters for more detailed analysis Ex. 5 - Deliberative Process (attaching list of commenters)
Meeting with DGA folks

To: Barash, Shari[Barash.Shari@epa.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Martinez, Menchu[martinez.menchu-c@epa.gov]
From: Larimer, Lisa
Sent: Thur 10/8/2015 5:45:01 PM
Subject: RE: Update on FDA-EPA fish advice - input requested

I'm on it. In between conferences.

From: Barash, Shari
Sent: Thursday, October 08, 2015 1:00 PM
To: Wathen, John
Cc: Larimer, Lisa; Martinez, Menchu
Subject: Re: Update on FDA-EPA fish advice - input requested

Lisa, if yours looks right, can you save as a pdf and resend?

Sent from my iPhone

On Oct 8, 2015, at 12:35 PM, Wathen, John <Wathen.John@epa.gov> wrote:

> Lisa-
>
> I can't get option 1 to format properly. The lower boxes end up on a second page.
>
> I am providing klutsie looking copies to Evelyn M., but you might need to work with her to get some better prints.
>
> I am leaving the office in 2 mins.
>
> ~John
>
> **From:** Larimer, Lisa

Sent: Thursday, October 08, 2015 11:02 AM
To: Deener, Kathleen
Cc: Southerland, Elizabeth; Hisel-Mccoy, Sara; Wathen, John
Subject: Update on FDA-EPA fish advice - input requested

Kacee-

We have made improvements to the fish advice materials after meeting with Tom Burke and others in ORD last week, multiple meetings with the Office of Children's Health Protection, and with FDA. I will focus on the changes to the chart, and I have attached two rough mock-ups. We are waiting to hear from Ex. 5 - Deliberative Process We are interested in hearing Ex. 5 - Deliberative Process preferably before the meeting with the Deputy Administrator this afternoon.

The changes are :

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Larimer, Lisa
Sent: Wed 8/19/2015 6:51:32 PM
Subject: Please read through changes to fish advice Q&As and technical web page
Fish Advice Qs and As-8.18.15_clean.docx
technical web page-fish advice-08.18.15 clean.docx
Fish Advice Qs and As-8.13.15 (RO 8-14-15).docx
technical web page-fish advice-072315 (RO 7-29-15) (2) dcs 8.6.15 (RO 8-5-15).PT_dcs 8.12.15 (RO 8-14-15) (RO 8-17-15)8.18.15.docx

I just discovered that lots of email from Sharon and Debbie has gone into my junk email folder. So far nothing catastrophic. FDA is suddenly on the super fast track again – they'd like to finalize everything tomorrow.

If you can before tomorrow's call (the meeting will be a call instead), read through the changes and flag any that are problematic. If you won't be on tomorrow's call, let me know what your issues are. Debbie will be sending more documents throughout the afternoon. Hopefully she will cc you. If she doesn't I'll forward, but I'll need to keep an eye on my junk folder in case it goes there.

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Wednesday, August 19, 2015 2:44 PM
To: Natanblut, Sharon; Wathen, John; Larimer, Lisa; Bigler, Jeff; Jones, William
Subject: RE: HOLD: FDA-EPA meeting to consolidate edits

Opps…forgot the attachments.

Here they are.

debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Smegal, Deborah
Sent: Wednesday, August 19, 2015 9:33 AM
To: Natanblut, Sharon; Wathen, John; Larimer, Lisa; Bigler, Jeff; Jones, William
Subject: RE: HOLD: FDA-EPA meeting to consolidate edits

Hi,

Here are 2 of the cleared documents (Q and As and technical appendix) that I cleaned up by accepting the track changes and removing the comment bubbles. I also re-read to fix spacing and punctuation.

Attached are both the clean version (dated 8.18.15) and also the OCC cleared version in track changes.

I will get the final NOA (FR notice) and comment summary table and send shortly.

Hope this assists.

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Natanblut, Sharon
Sent: Wednesday, August 19, 2015 9:27 AM
To: Wathen, John; Larimer, Lisa; Bigler, Jeff; Smegal, Deborah; Jones, William
Subject: RE: HOLD: FDA-EPA meeting to consolidate edits

Fine with me. Deb, do you have the latest versions of everything you can send around?

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Wednesday, August 19, 2015 8:55 AM
To: Larimer, Lisa; Bigler, Jeff; Smegal, Deborah; Natanblut, Sharon; Jones, William
Subject: RE: HOLD: FDA-EPA meeting to consolidate edits

Maybe an abbreviated telephone check-in?

~John

From: Larimer, Lisa
Sent: Tuesday, August 18, 2015 5:00 PM
To: Wathen, John; Bigler, Jeff; Deborah Smegal (Deborah.smegal@fda.hhs.gov); Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov); Bill Jones (William.jones@fda.hhs.gov)
Subject: RE: HOLD: FDA-EPA meeting to consolidate edits

Do we still need to have this meeting?

-----Original Appointment-----
From: Larimer, Lisa
Sent: Thursday, August 06, 2015 1:57 PM
To: Larimer, Lisa; Wathen, John; Bigler, Jeff; Deborah Smegal (Deborah.smegal@fda.hhs.gov); Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov); Bill Jones (William.jones@fda.hhs.gov)
Subject: HOLD: FDA-EPA meeting to consolidate edits
When: Thursday, August 20, 2015 9:30 AM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: TBD

From: Larimer, Lisa
Location: DCRoomWest5231L/DC-CCW-OST
Importance: Normal
Subject: discuss fish advice
Start Date/Time: Wed 12/9/2015 7:00:00 PM
End Date/Time: Wed 12/9/2015 8:00:00 PM

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 10/8/2015 3:57:29 PM
Subject: RE: Ex. 5 - Deliberative Process

I assume we'll be able to Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, October 08, 2015 11:33 AM
To: Natanblut, Sharon; Jones, William; Larimer, Lisa; Wathen, John
Subject: FW: Ex. 5 - Deliberative Process

Hi Guys,

Just wanted you to see more details about the comparison we did between the 2010 and 2015 deliberative DGAs. I asked Brenna to do a cross walk and below is her email to me. We updated the graph, plan to cite DGA 2015 (rather than DGA 2010) pending approval.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Flannery, Brenna
Sent: Wednesday, October 07, 2015 11:09 AM
To: Smegal, Deborah
Subject: Ex. 5 - Deliberative Process

Hi Debbie – Please see what I found below. Judi and I will need to update the graph at the end of the Technical Appendix.

-

Where fish advice references Dietary Guidelines 2010:

Technical Appendix

Ex. 5 - Deliberative Process

Q's and A's

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

DGAs 2015 Wording:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Brenna Flannery, PhD

Toxicologist, Contaminant Assessment Branch

Division of Risk and Decision Analysis/OAO/CFSAN

Harvey W. Wiley Building (CPK1), Rm 2A-037

5100 Paint Branch Parkway

College Park, MD 20740

Brenna.flannery@fda.hhs.gov

Ph: 240-402-3081

To: Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]
From: Larimer, Lisa
Sent: Mon 9/28/2015 6:58:36 PM
Subject: RE: Email for ORD

Thank you!

From: Fontenelle, Samantha
Sent: Monday, September 28, 2015 2:55 PM
To: Larimer, Lisa
Subject: RE: Email for ORD

Lisa. Completed my review and all the numbers checked out. I reviewed Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Thanks,

Sam

From: Larimer, Lisa
Sent: Monday, September 28, 2015 1:00 PM
To: Hisel-Mccoy, Sara
Cc: Barash, Shari; Wathen, John; Fontenelle, Samantha
Subject: Email for ORD

Samantha is in the final throes of checking my results. She will let us know when she is done.

Here is the email. I also have it in a Word file if you prefer. Shari reviewed. Feel free to completely rewrite. ☺

KC and Fred –

We're following up with more information related to the FDA-EPA fish advice.

Focus on mercury

Ex. 5 - Deliberative Process

-

Other considerations

Ex. 5 - Deliberative Process

FINFISH/SHELLFISH	Mean Hg conc (ppm)
ANCHOVIES	0.02
BLUEFISH	0.37
BUFFALO FISH	0.14
CARP	0.11
CATFISH	0.02
CLAM	0.01
COD	0.11
CRAB	0.06
CRAWFISH	0.03
CROAKER, ATLANTIC	0.07
CROAKER, WHITE	0.29
FLATFISH: FLOUNDER	0.05
FLATFISH: PLAICE	0.04
FLATFISH: SOLE	0.08
GROUPER	0.45
HADDOCK	0.06
HAKE	0.08
HALIBUT	0.24
HERRING	0.08
LOBSTER, AMERICAN	0.11
LOBSTER, SPINY	0.09

Ex. 5 - Deliberative Process

MAHI MAHI	0.18
MARLIN	0.49
MONKFISH	0.16
MULLET	0.05
ORANGE ROUGHY	0.57
OYSTER	0.01
PERCH, FRESHWATER	0.15
PERCH, OCEAN	0.12
PICKEREL	0.09
POLLOCK	0.03
ROCKFISH	0.23
SABLE FISH	0.36
SALMON	0.02
SALMON, CANNED	0.01
SARDINE	0.01
SCALLOP	0.00
SCORPIONFISH	0.23
SEA BASS, BLACK	0.13
SEA BASS, CHILEAN	0.35
SEA BASS, STRIPED	0.07
SHAD	0.04
SHARK	0.98
SHEEPSHEAD	0.09
SHRIMP	0.01
SMELT	0.08
SNAPPER	0.17
SQUID	0.02
SWORDFISH	1.00
TILAPIA	0.01
TILEFISH, ATLANTIC	0.14
TROUT, FRESHWATER	0.07
TUNA, CANNED	

Ex. 5 - Deliberative Process

(ALBACORE)	
TUNA, CANNED (LIGHT)	0.13
TUNA, FR/FZN ALBACORE	0.36
TUNA, FR/FZN BIGEYE	0.69
TUNA, FR/FZN SKIPJACK	0.14
TUNA, FR/FZN YELLOWFIN	0.35
WEAKFISH (SEA TROUT)	0.23
WHITEFISH	0.09
WHITING	0.05

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; McPeak, Holly (OS)[Holly.McPeak@hhs.gov]; Casavale, Kellie (OS)[Kellie.Casavale@hhs.gov]
Cc: Wathen, John[Wathen.John@epa.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 8/19/2015 6:08:19 PM
Subject: RE: Seafood- updating Appendix 11 --

I can make either of those days work.

-Lisa

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Wednesday, August 19, 2015 1:40 PM
To: Jones, William; McPeak, Holly (OS); Casavale, Kellie (OS)
Cc: Larimer, Lisa; Wathen, John; Natanblut, Sharon
Subject: RE: Seafood- updating Appendix 11 --

Hi,

I prefer the Tuesday time, but could participate part of the time on Weds.

debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Jones, William
Sent: Wednesday, August 19, 2015 11:27 AM
To: McPeak, Holly (OS); Casavale, Kellie (OS)
Cc: Smegal, Deborah; Larimer, Lisa; Wathen, John; Natanblut, Sharon
Subject: RE: Seafood- updating Appendix 11 --

Either of those times could work for me.

Thanks,

Bill

William R. Jones, Ph.D.

Acting Deputy Director, Office of Food Safety

Center for Food Safety and Applied Nutrition, USFDA

5100 Paint Branch Parkway

College Park, MD 20740

From: McPeak, Holly (HHS/OASH) [mailto:Holly.McPeak@hhs.gov]
Sent: Wednesday, August 19, 2015 9:34 AM
To: Natanblut, Sharon; Casavale, Kellie (OS)
Cc: Jones, William; Smegal, Deborah; Larimer, Lisa; Wathen, John
Subject: RE: Seafood- updating Appendix 11 --

Dear Sharon,

Let us know if you all have availability on Tuesday after 1:00 through 3:30 or Wednesday between 9: 00 and 12:00? (We will be able to invite the USDA folks).

Feel free to call me about scheduling or if you would like us to review any drafts in advance of the meeting ! I'll be happy to share!

Holly H. McPeak, MS

Nutrition Advisor, HHS/ODPHP

Holly.McPeak@hhs.gov

(240) 453-8267

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Wednesday, August 19, 2015 9:25 AM
To: Casavale, Kellie (OS/OASH); McPeak, Holly (HHS/OASH)
Cc: Jones, William; Smegal, Deborah (FDA/CFSAN); Larimer, Lisa; Wathen, John
Subject: RE: Seafood- updating Appendix 11 --

Looking forward to it.

From: Casavale, Kellie (OS/OASH) [mailto:Kellie.Casavale@hhs.gov]
Sent: Wednesday, August 19, 2015 9:11 AM
To: Natanblut, Sharon; McPeak, Holly (OS)
Cc: Jones, William; Smegal, Deborah; Larimer, Lisa; Wathen, John
Subject: RE: Seafood- updating Appendix 11 --

Next week would be great. I will be on a plane back to the east coast on Monday. Holly will be in touch to coordinate. Thanks!

Kellie

Kellie O. Casavale, PhD, RD

Nutrition Advisor, Division of Prevention Science

Co-Executive Secretary, (former) 2015 Dietary Guidelines Advisory Committee

HHS, Office of Disease Prevention and Health Promotion

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Wednesday, August 19, 2015 9:06 AM
To: Casavale, Kellie (OS/OASH); McPeak, Holly (HHS/OASH)
Cc: Jones, William; Smegal, Deborah (FDA/CFSAN); Larimer, Lisa; Wathen, John
Subject: RE: Seafood- updating Appendix 11 --

That would be terrific! Yes, I think an hour would be good. I'm looping in our EPA colleagues for their awareness. We would be pleased to have them join us if they wish or we could meet with you first and then brief them to see if they want to follow-up.

Could we schedule it for next week? I will be unavailable most of September and we'd really like to meet beforehand.

Many thanks.

Sharon

From: Casavale, Kellie (OS/OASH) [mailto:Kellie.Casavale@hhs.gov]
Sent: Wednesday, August 19, 2015 6:50 AM
To: Natanblut, Sharon; McPeak, Holly (OS)
Cc: Jones, William; Smegal, Deborah
Subject: RE: Seafood- updating Appendix 11 --

Wonderful! Thanks, Sharon. Holly McPeak (copied) is going to help us all find a time for a call. Will an hour be adequate? Is it ok if we also include Eve Essery Study at CNPP/USDA? ODPHP and CNPP develop the Dietary Guidelines together. The discussion will be confidential.

Kellie

Kellie O. Casavale, PhD, RD

Nutrition Advisor, Division of Prevention Science

Co-Executive Secretary, (former) 2015 Dietary Guidelines Advisory Committee

HHS, Office of Disease Prevention and Health Promotion

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, August 18, 2015 6:48 PM
To: Casavale, Kellie (OS/OASH); McPeak, Holly (HHS/OASH)
Cc: Jones, William; Smegal, Deborah (FDA/CFSAN)
Subject: RE: Seafood- updating Appendix 11 --
Importance: High

Hi there,

I was asked to reach out to you on behalf of FDA and EPA to discuss the fish advice that we are in the process of finalizing. We would love to talk with you as soon as possible about this subject and to share with you what we plan to release. I should add that these materials have not yet been sent through formal review to HHS and so we just received the go-ahead by Jeremy Sharp to be able to share these with you on an informal basis. Does that work for you?

Would you please let me know how soon you would be available? We are so pleased that you reached out.

Sharon Natanblut

Senior Advisor to the Deputy Commissioner/

Director, Strategic Communications and Public Engagement

FDA Foods and Veterinary Medicine Program

301 796 5099

From: McPeak, Holly (HHS/OASH) [mailto:Holly.McPeak@hhs.gov]
Sent: Tuesday, August 04, 2015 1:15 PM
To: Jones, William
Subject: FW: Seafood- updating Appendix 11

Dear Bill,

Hi! You come highly recommended, Bill! We would like to have a call with you regarding Fish and Mercury as we update our nutrition guidance for 2015 See Kellie Casavale's request below. I would like to coordinate a conference call with you!

Are you free by chance Wed or Thursday at 1:15- 2:00 or after 11:00 on Friday? We think this should take only 45 minutes!

Also, do you have a contact at EPA that you work with on the topic? We would like to include EPA as well!

Thanks! Please contact me if you have any questions!

Holly McPeak

Nutrition Advisor

HHS/ODPHP

Rockville, MD

240-453-8267

From: Trumbo, Paula [mailto:Paula.Trumbo@fda.hhs.gov]
Sent: Friday, July 31, 2015 12:51 PM
To: McPeak, Holly (HHS/OASH)
Cc: Rivers, Crystal (FDA/CFSAN)
Subject: RE: Seafood- updating Appendix 11

Hi Holly - Bill Jones has taken over this project – his email address is

William.jones@fda.hhs.gov He is located in the seafood division here at CFSAN.

Hope all is well.

Paula

From: McPeak, Holly (HHS/OASH) [mailto:Holly.McPeak@hhs.gov]
Sent: Friday, July 31, 2015 12:35 PM
To: Trumbo, Paula
Cc: Rivers, Crystal
Subject: FW: Seafood- updating Appendix 11

Hey Paula,

Do you have a contact person who may have worked with Phil Spiller on Seafood information? Or a Mercury expert? We want to set up call soon Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process ...Any leads will be helpful!

Hope you are having a good summer! ☺

Holly H. McPeak, MS

Nutrition Advisor, HHS/ODPHP

Holly.McPeak@hhs.gov

(240) 453-8267

From: Casavale, Kellie (OS/OASH)
Sent: Wednesday, July 29, 2015 4:49 PM
To: McPeak, Holly (HHS/OASH)
Cc: Olson, Richard (HHS/OASH)
Subject: Seafood- updating Appendix 11

We are working on updating the 2010 DGA appendix 11 that provides the seafood varieties and the amounts of EPA+ DHA and methyl mercury. Could you help us in identifying some contacts and setting up some discussion for us (and USDA, probably Eve)? We need the staff contact with… (Phil Spiller is gone, but Shirley Blakeley may know.)

- **FDA and EPA** on their "Fish: What Pregnant Women and Parents Should Know Draft Updated Advice by FDA and EPA" (http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm393070.htm)

  - Are these contacts also the experts on mercury data? If not, who is? Reference: Mercury Concentrations in Fish: FDA Monitoring Program (1990-2010) shows mercury levels over time.

http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm191007.htm

We have a number of questions for them and we'll ask them Ex. 5 - Deliberative Process I can create an agenda for the discussion. Next week (or as soon as is feasible) would be great and we can do it by phone.

Kellie

Kellie O. Casavale, PhD, RD

Nutrition Advisor, Division of Prevention Science

Co-Executive Secretary, (former) 2015 Dietary Guidelines Advisory Committee

HHS, Office of Disease Prevention and Health Promotion

1101 Wootton Pkwy, LL117

Rockville, MD 20852

(240) 453-8252

www.DietaryGuidelines.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/13/2015 1:57:07 PM
Subject: RE: getting organized to brief Tom Burke on fish advice

☺

From: Wathen, John
Sent: Thursday, August 13, 2015 9:56 AM
To: Larimer, Lisa
Subject: RE: getting organized to brief Tom Burke on fish advice

Well, at least we have our stories straight…

~John

From: Larimer, Lisa
Sent: Thursday, August 13, 2015 9:50 AM
To: Schoeny, Rita; Wathen, John; Fontenelle, Samantha; Bigler, Jeff
Cc: Cantilli, Robert; Hauchman, Fred; Fegley, Robert
Subject: RE: getting organized to brief Tom Burke on fish advice

The Admin briefing has not been scheduled yet. We're on a temporary hold until we meet with the Dietary Guidelines folks **Ex. 5 - Deliberative Process** Hopefully that will happen next week and then we'll be back on track.

From: Schoeny, Rita
Sent: Thursday, August 13, 2015 9:15 AM
To: Wathen, John; Larimer, Lisa; Fontenelle, Samantha; Bigler, Jeff
Cc: Cantilli, Robert; Hauchman, Fred; Fegley, Robert
Subject: RE: getting organized to brief Tom Burke on fish advice

Hi. We are going to brief Tom Burke and Bob Kavlock as soon as we can get on their calendars. Has the briefing for Gina been scheduled yet? RSVP.

From: Wathen, John
Sent: Tuesday, August 11, 2015 2:37 PM
To: Schoeny, Rita; Larimer, Lisa; Fontenelle, Samantha; Bigler, Jeff
Cc: Cantilli, Robert
Subject: RE: getting organized to brief Tom Burke on fish advice

Yes- the vastness of HHS. I was there for a long time, then they finally got the HHS OK and it went out for comment 6/11/14. –I'm going to bullets so it looks like a chronology

•□□□□□□□ First FACA was the CHPAC -9/10/14 That was pretty good, and they put out a good letter report

http://www2.epa.gov/sites/production/files/2015-01/documents/chpac_final_fish_advisory_recommendations.pdf

http://www2.epa.gov/sites/production/files/2015-01/documents/fish_advisory_letter_appendices.pdf

•□□□□□□□ Then there was FDA's Risk Communication AC 11/3-4/14. There were some substantive presentations and written comments, but most of the stronger comments on both sides were repeated in the comments to the docket.

•□□□□□□□ The end of 2014/beginning of 2015, Ex. 6 - Personal Privacy Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process Ex. 6 - Personal Privacy

•□□□□□□□ The new year brought new teams- Sharon Natanblut, Bill Jones, Deborah Smeagle

(former EPA OPPTS) for FDA; Lisa Larimer, Bigler, and myself for EPA. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

As. FDA folks played straight pool with us

By the way, we had some great comments- states, enviros, academia. A lot of comments on the RBA, to which we did not respond as being outside the scope. My favorite was Phillipe Grandjean which I am attaching. You have the response to comments document which captures the various flavors on the draft advice. I digress.

•□□□□□□ Comments closed 3/26. We wrote them up, finished our work with the FDA group (almost).

•□□□□□□ April 2015- We commented on the element in the 2015 DGAC Report that

Ex. 5 - Deliberative Process

•□□□□□□ Right now, FDA is trying to get clearance from their OGC to share the docs with the rest of HHS and USDA Ex. 5 - Deliberative Process We were otherwise ready to brief Gina at Ken K.'s suggestion. Briefed him 8/3. Hopefully that will play out quickly.

That's about it M'am. Further questions let me know.

~John

From: Schoeny, Rita
Sent: Tuesday, August 11, 2015 1:30 PM
To: Wathen, John; Larimer, Lisa; Fontenelle, Samantha; Bigler, Jeff
Cc: Cantilli, Robert
Subject: getting organized to brief Tom Burke on fish advice

Hi, all. Putting together some material for Tom B in advance of any meeting with Gina. I plan to steal the PPT you used with Ken as well as the fish advice, Q and A etc.

But for background, can you tell me in a couple of sentences what happened with the advice between summer 2012 (when I have my last notes) and now. I recall that we and FDA sent draft advice with Q and A to HHS; I remember that we got EPA sign off on a draft FR, etc. And then I thought that the advice disappeared into the vastness of HHS. And then . . . (I know Tom B will ask about any post 2012 FACA as well as the public comments).

RSVP. I would like to get goodies over to Tom in a day or two. Thanks.

Rita Schoeny, Ph.D.
Senior Science Advisor, Office of Science Policy
Office of Research and Development
U.S. Environmental Protection Agency
Room 51134 RRB
1200 Pennsylvania Avenue NW (8104R)
Washington DC 20460-0001

202-566-1127
202-565-2911 fax

Address for delivery:
1300 Pennsylvania Ave. NW
Room# 51134 MC8104R
Washington DC 20004

To: Jones, William[William.Jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Fri 12/4/2015 7:45:25 PM
Subject: RE: NIH comment

So, then is Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process I wish Jeff were working so we could ask him. Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Tuesday, November 24, 2015 2:24 PM
To: Wathen, John <Wathen.John@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Subject: RE: NIH comment

Thanks – and Happy TG to you!

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Tuesday, November 24, 2015 2:18 PM
To: Jones, William; Larimer, Lisa
Cc: Smegal, Deborah; Natanblut, Sharon
Subject: Re: NIH comment

Bill-

I believe that the comment makes more sense as "wouldn't". Any rate I hope that we

Ex. 5 - Deliberative Process

Fresh waters are typically what state fish and game departments focus on. In Maine, with which I am familiar, there is a different agency (DMR) involved as opposed to

Inland Fish and Wildlife for the fresh waters.

Ex. 5 - Deliberative Process

Have a good TG. y'all.

~John

From: Jones, William <William.Jones@fda.hhs.gov>
Sent: Tuesday, November 24, 2015 1:59 PM
To: Larimer, Lisa; Wathen, John
Cc: Smegal, Deborah; Natanblut, Sharon
Subject: NIH comment

This is an NIH comment we've been asked to address. I think it is supposed to say "…why would**n't** the same Ex. 5 - Deliberative Process …"? Anyway, is this something you happen to have dealt with before or that you otherwise might have a good answer for?

NIH Comment – Fish Chart

With regard to the advice pertaining to fish caught be family or friends, why would the same

Ex. 5 - Deliberative Process

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Tue 12/1/2015 8:37:42 PM
Subject: FW: Informal Testing of Advice About Eating Fish
Seafood Advice_Message Testing Report_Final_20151116.pdf

Bottom line is Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, November 30, 2015 3:47 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>
Subject: FW: Informal Testing of Advice About Eating Fish

As promised, here's the testing we did.

To: Klasen, Matthew[Klasen.Matthew@epa.gov]; Conerly, Octavia[Conerly.Octavia@epa.gov]
Cc: Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/6/2015 9:38:20 PM
Subject: RE: Any changes to the fish advice materials since Monday's briefing for Ken?

Sorry, I couldn't get back into my computer. Stupid nonfunctioning card reader.

After discussing with Sara and Betsy, we'd like to hold off on briefing the Administrator until after we meet with the HHS/USDA folks on the Dietary Guidelines and make sure there are no issues. We hope to meet with them within the next 2 weeks.

I know a potential issue is that then we'll be getting into travel/vacation schedules for Ken, Ellen, etc. If Ken still wants to have a briefing in the next week or two, we understand.

I'm out of the office until Monday. Sara Hisel-McCoy has my files for the briefing request and memo.

Thanks,

Lisa

From: Klasen, Matthew
Sent: Thursday, August 06, 2015 3:49 PM
To: Larimer, Lisa; Conerly, Octavia
Cc: Bethel, Heidi
Subject: RE: Any changes to the fish advice materials since Monday's briefing for Ken?

Hey Lisa – any updates?

Thanks,
Matt

From: Larimer, Lisa
Sent: Thursday, August 06, 2015 1:26 PM
To: Conerly, Octavia; Klasen, Matthew
Cc: Bethel, Heidi
Subject: RE: Any changes to the fish advice materials since Monday's briefing for Ken?

I don't envision making any substantive changes, but wanted to give you all a heads up that the timing of the meeting with the Administrator may need to change (we may need more time if an issue pops up in a meeting with HHS/USDA next week). I'll know more by 3:15 today.

From: Conerly, Octavia
Sent: Thursday, August 06, 2015 12:43 PM
To: Klasen, Matthew; Larimer, Lisa
Cc: Bethel, Heidi
Subject: RE: Any changes to the fish advice materials since Monday's briefing for Ken?

Matt,

I don't think any changes have been made since Monday but I would wait for Lisa to confirm. She's meeting with her DD right now.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Klasen, Matthew
Sent: Thursday, August 06, 2015 12:40 PM
To: Conerly, Octavia; Larimer, Lisa
Cc: Bethel, Heidi
Subject: Any changes to the fish advice materials since Monday's briefing for Ken?

Octavia and Lisa,

Separate from (but related to) the process of submitting the meeting request form – which hopefully you're also working on – I wanted to check in to see if there have been any meaningful changes made to the attached two documents since the meeting with Ken on Monday.

The reason I'm asking is that Stan Meiburg will be out of the office for the next two weeks, starting on Monday, and will therefore most likely miss the impending briefing for the Administrator. We'd like to give Stan a copy of these docs for his awareness (and comments, if any) before he leaves, as somewhat of a substitute for his participation in the briefing. Ken is comfortable with this approach, and I just wanted to double check with you to make sure there weren't any changes that have been made since Monday.

Please let me know; I'm planning to give Stan a copy this afternoon and will use these versions unless I hear otherwise.

Thanks,
Matt

From: Bethel, Heidi
Sent: Tuesday, August 04, 2015 8:03 AM

To: Conerly, Octavia; Larimer, Lisa
Cc: Klasen, Matthew; Naples, Eileen
Subject: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Hi Octavia and Lisa,

Would the two of you please work on a meeting request form for the Fish Advice meeting with the Administrator? I have informed Matt and Eileen that this will be coming their way to schedule. Please let me know how I may help. Ken indicated that we should have the meeting with the Administrator in the next week or two.

Thanks,

Heidi

(202) 566-2054

From: Bethel, Heidi
Sent: Monday, August 03, 2015 3:43 PM
To: Naples, Eileen
Cc: Klasen, Matthew; Conerly, Octavia; Penman, Crystal
Subject: Meeting Request coming your way! Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Hi Eileen,

Our program office briefed Ken on the FDA/ EPA fish consumption advice this afternoon and Ken asked for a half hour briefing with the Administrator within a week or two time frame. It is timely, but not urgent. OW would like to release the advice in September we are possibly looking for an Administrator level announcement jointly with FDA. This issue was previously handled mostly at the Bob Sussman level. I can work with OST on a meeting request in the next day, but wanted to give you a heads up on this item.

Thanks,

Heidi

(202) 566-2054

Subject: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Location: 3233 WJCE

Start: Mon 8/3/2015 1:00 PM

End: Mon 8/3/2015 1:30 PM

Recurrence: (none)

Meeting Status: Meeting organizer

Organizer: Kopocis, Ken

Required Attendees: Southerland, Elizabeth; Hisel-Mccoy, Sara; Larimer, Lisa; Bigler, Jeff; Wathen, John

Optional Attendees: Naidenko, Olga; Conerly, Octavia; Gilinsky, Ellen; Penman, Crystal; Fontenelle, Samantha

Poc Lisa Larimer 202-566-1017

To: Bethel, Heidi[Bethel.Heidi@epa.gov]; Conerly, Octavia[Conerly.Octavia@epa.gov]
Cc: Penman, Crystal[Penman.Crystal@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/6/2015 4:24:16 PM
Subject: RE: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code: Ex. 6 - Personal Privacy

I have a meeting with Sara in 7 minutes. I'm sure she wants to see them before they go up, so I hope to grab her then and get her clearance. Thanks you two!

From: Bethel, Heidi
Sent: Thursday, August 06, 2015 12:22 PM
To: Conerly, Octavia; Larimer, Lisa
Cc: Penman, Crystal
Subject: RE: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code: Ex. 6 - Personal Privacy

Octavia and Lisa,

Thanks! I will look for the Administrator meeting request today. I leave at 4 pm today and I believe Crystal Penman does as well. Crystal will be in the office tomorrow, but I will not be. Please be sure to CC both of us when you send it up so we can show it to Ken.

Thanks,

Heidi

From: Conerly, Octavia
Sent: Thursday, August 06, 2015 11:50 AM
To: Larimer, Lisa
Cc: Bethel, Heidi
Subject: RE: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code: Ex. 6 - Personal Privacy

Thank you Lisa.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

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PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Larimer, Lisa
Sent: Thursday, August 06, 2015 11:10 AM
To: Conerly, Octavia
Cc: Bethel, Heidi
Subject: RE: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Sorry, got sidelined by more pressing stuff. Thought I was all set yesterday then found out there was a second form (briefing memo) to fill out. Working on that now.

From: Conerly, Octavia
Sent: Thursday, August 06, 2015 8:19 AM
To: Larimer, Lisa
Subject: Fwd: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Oops! Meant to send this to u Lisa. Thanks for the catch Heidi.

Sent from my iPhone

Begin forwarded message:

From: "Bethel, Heidi" <Bethel.Heidi@epa.gov>

Date: August 6, 2015 at 7:39:28 AM EDT
To: "Conerly, Octavia" <Conerly.Octavia@epa.gov>
Subject: RE: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy **participant code** Ex. 6 - Personal Privacy

HI OC,

You didn't include Lisa on your e-mail.

How are you doing? Everything OK?

Thanks for taking care of this Octavia.

Heidi

From: Conerly, Octavia
Sent: Thursday, August 06, 2015 7:38 AM
To: Bethel, Heidi
Subject: Re: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Lisa, let me know if u need help.

Sent from my iPhone

On Aug 6, 2015, at 7:00 AM, Bethel, Heidi <Bethel.Heidi@epa.gov> wrote:

> Hi Lisa and Octavia,
>
> Did this meeting request for the fish advice meeting with the Administrator come up to Crystal and Ken? I'm hoping we can get it processed today so we can get it up on the calendar. Let me know if I may help. I am out of the office tomorrow.
>
> Thanks,
>
> Heidi

From: Bethel, Heidi

Sent: Wednesday, August 05, 2015 8:59 AM
To: Conerly, Octavia; Larimer, Lisa
Cc: Klasen, Matthew
Subject: Re: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

I just spoke to Ken about this to let him know that the meeting request is moving. He asked that I also loop in Travis and OPA as the fish consumption advice is likely to reach the national news level, as discussed in the meeting with Ken. I will alert Travis today.

Heidi

From: Conerly, Octavia
Sent: Wednesday, August 5, 2015 8:20 AM
To: Bethel, Heidi; Larimer, Lisa
Cc: Klasen, Matthew
Subject: RE: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Thanks Heidi.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Bethel, Heidi
Sent: Wednesday, August 05, 2015 7:20 AM
To: Larimer, Lisa
Cc: Conerly, Octavia; Klasen, Matthew
Subject: Re: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Hi Lisa,

Apologies for not sending this to you yesterday. I didn't se eyour e-mail until this morning. This is the only copy I have of the Admin meeting request form, see p. 13.

I'm in the midst of a computer transfer today/ tomorrow and am running off of webmail because I'm having problems with Outlook.

Hope we can get this done today.

Thanks for your help and let me know if you need anything else.

Heidi

(202) 566-2054

From: Larimer, Lisa
Sent: Tuesday, August 4, 2015 9:59 AM
To: Bethel, Heidi
Subject: RE: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Heidi,

Do you have it handy? I never can be certain if the ones we have on share drives, etc are the most recent version.

Thanks!

Lisa

From: Bethel, Heidi
Sent: Tuesday, August 04, 2015 8:10 AM
To: Conerly, Octavia
Cc: Larimer, Lisa; Klasen, Matthew; Naples, Eileen
Subject: RE: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Do you need the form?

From: Conerly, Octavia
Sent: Tuesday, August 04, 2015 8:09 AM
To: Bethel, Heidi
Cc: Larimer, Lisa; Klasen, Matthew; Naples, Eileen
Subject: Re: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Heidi,

I am working from home today.

Lisa, I am not sure if Jeanette is in the office today. So please make sure you include me when you send the invite forward. Thank you.

Sent from my iPhone

On Aug 4, 2015, at 8:03 AM, Bethel, Heidi <Bethel.Heidi@epa.gov> wrote:

> Hi Octavia and Lisa,
>
> Would the two of you please work on a meeting request form for the Fish Advice

meeting with the Administrator? I have informed Matt and Eileen that this will be coming their way to schedule. Please let me know how I may help. Ken indicated that we should have the meeting with the Administrator in the next week or two.

Thanks,

Heidi

(202) 566-2054

From: Bethel, Heidi
Sent: Monday, August 03, 2015 3:43 PM
To: Naples, Eileen
Cc: Klasen, Matthew; Conerly, Octavia; Penman, Crystal
Subject: Meeting Request coming your way! Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Hi Eileen,

Our program office briefed Ken on the FDA/ EPA fish consumption advice this afternoon and Ken asked for a half hour briefing with the Administrator within a week or two time frame. It is timely, but not urgent. OW would like to release the advice in September we are possibly looking for an Administrator level announcement jointly with FDA. This issue was previously handled mostly at the Bob Sussman level. I can work with OST on a meeting request in the next day, but wanted to give you a heads up on this item.

Thanks,

Heidi

(202) 566-2054

Subject: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Location: 3233 WJCE

Start: Mon 8/3/2015 1:00 PM

End: Mon 8/3/2015 1:30 PM

Recurrence: (none)

Meeting Status: Meeting organizer

Organizer: Kopocis, Ken

Required Attendees: Southerland, Elizabeth; Hisel-Mccoy, Sara; Larimer, Lisa; Bigler, Jeff; Wathen, John

Optional Attendees: Naidenko, Olga; Conerly, Octavia; Gilinsky, Ellen; Penman, Crystal; Fontenelle, Samantha

Poc Lisa Larimer 202-566-1017

<FISH_CHART_H_7.24.pdf>

<draft FR notice-fish advice.Version 1.docx>

<Briefing agenda.doc>

<FDA-EPA Fish Advice briefing.pptx>

<Joint FDA_EPA Fish Advice_07_13_2015.pdf>

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
Cc: Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Larimer, Lisa
Sent: Thur 8/6/2015 3:09:52 PM
Subject: RE: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Sorry, got sidelined by more pressing stuff. Thought I was all set yesterday then found out there was a second form (briefing memo) to fill out. Working on that now.

From: Conerly, Octavia
Sent: Thursday, August 06, 2015 8:19 AM
To: Larimer, Lisa
Subject: Fwd: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Oops! Meant to send this to u Lisa. Thanks for the catch Heidi.

Sent from my iPhone

Begin forwarded message:

From: "Bethel, Heidi" <Bethel.Heidi@epa.gov>
Date: August 6, 2015 at 7:39:28 AM EDT
To: "Conerly, Octavia" <Conerly.Octavia@epa.gov>
Subject: RE: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy **participant code** Ex. 6 - Personal Privacy

HI OC,

You didn't include Lisa on your e-mail.

How are you doing? Everything OK?

Thanks for taking care of this Octavia.

Heidi

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Sent: Thursday, August 06, 2015 7:38 AM
To: Bethel, Heidi
Subject: Re: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in

855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Lisa, let me know if u need help.

Sent from my iPhone

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> Hi Lisa and Octavia,
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I just spoke to Ken about this to let him know that the meeting request is moving. He asked that I also loop in Travis and OPA as the fish consumption advice is likely to reach the national news level, as discussed in the meeting with Ken. I will alert Travis today.

Heidi

From: Conerly, Octavia
Sent: Wednesday, August 5, 2015 8:20 AM
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Cc: Klasen, Matthew
Subject: RE: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Thanks Heidi.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

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Cc: Larimer, Lisa; Klasen, Matthew; Naples, Eileen
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From: Bethel, Heidi
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To: Naples, Eileen
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Hi Eileen,

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Thanks,

Heidi

(202) 566-2054

Subject: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Location: 3233 WJCE

Start: Mon 8/3/2015 1:00 PM

End: Mon 8/3/2015 1:30 PM

Recurrence: (none)

Meeting Status: Meeting organizer

Organizer: Kopocis, Ken

Required Attendees: Southerland, Elizabeth; Hisel-Mccoy, Sara; Larimer, Lisa; Bigler, Jeff; Wathen, John

Optional Attendees: Naidenko, Olga; Conerly, Octavia; Gilinsky, Ellen; Penman, Crystal; Fontenelle, Samantha

Poc Lisa Larimer 202-566-1017

<FISH_CHART_H_7.24.pdf>

<draft FR notice-fish advice.Version 1.docx>

<Briefing agenda.doc>

<FDA-EPA Fish Advice briefing.pptx>

<Joint FDA_EPA Fish Advice_07_13_2015.pdf>

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Fri 11/20/2015 8:39:11 PM
Subject: Can you take a quick look at this?
Ex. 5 - Deliberative Process fish advice-112015.docx

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Mon 10/5/2015 12:06:28 PM
Subject: RE: Meeting with Stan Meiburg next week

I'm going to head straight there from home. With the number Of Metro advisories in my inbox already, I have the feeling it will be a long trip.

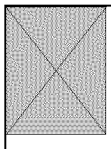
From: Wathen, John
Sent: Friday, October 02, 2015 3:55 PM
To: Larimer, Lisa
Subject: Re: Meeting with Stan Meiburg next week

Call it a half hour on the Metro from Archive. I think I'll plan to leave the office shortly before 9. I want to pick some stuff up and I could bring current documents for both of us.

~John

•□□□□□□□ **Rail Departs from**

ARCHIVES METRO STATION



Metro - Rail - Archives-Navy Memorial-Penn Quarter

Washington Metropolitan Area Transit Authority: Rail ... Parking: None Bikes: Bikesharing is available near or at this station.

Read more...

at 8:05am

Board

GREEN LINE Rail
towards GREENBELT

Arrive

COLLEGE PARK/U OF MD METRO STATION at 8:28am

There are active advisories that may affect your trip: View advisories

---

From: Larimer, Lisa
Sent: Friday, October 2, 2015 3:39 PM
To: Wathen, John
Subject: RE: Meeting with Stan Meiburg next week

I need to revisit how long the trip takes. Not sure if I'll stop by the office or go straight there

From: Wathen, John
Sent: Friday, October 02, 2015 1:42 PM
To: Larimer, Lisa
Subject: Re: Meeting with Stan Meiburg next week

Lisa-

I will be coming onto the office 1st thing Mon before I/we head up to CP.

~John

From: Larimer, Lisa
Sent: Friday, October 2, 2015 10:19:27 AM
To: Southerland, Elizabeth; Wathen, John; Barash, Shari; Hisel-Mccoy, Sara
Subject: RE: Meeting with Stan Meiburg next week

Will do! We'll be at FDA on Monday morning.

From: Southerland, Elizabeth
Sent: Friday, October 02, 2015 10:18 AM
To: Larimer, Lisa; Wathen, John; Barash, Shari; Hisel-Mccoy, Sara
Subject: Meeting with Stan Meiburg next week

Ken is setting up a meeting with Stan Meiburg early next week to discuss the Fish Advice issue. He was unable to get this scheduled for today. In the meantime, you should continue to work

Ex. 5 - Deliberative Process

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Wed 8/5/2015 4:56:29 PM
Subject: Thoughts on invitees to Admin briefing on fish advice?

Typing up the request got bumped back to me. Everyone and their brother is asking to be invited (e.g., OSP, communications). Who am I missing? Are there folks I should push back on and not invite? Here's who I have so far:

EPA Staff (Required): Lisa Larimer, John Wathen, Sara Hisel-McCoy, Elizabeth Southerland, Ken Kopocis, Thomas Burke

EPA Staff (Optional): Jeff Bigler, Travis Loop, Cara Lalley, Robert Kavlock, Fred Hauchman, Rita Schoeny

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Fri 11/20/2015 2:37:08 PM
Subject: FW: Updated & shortened options for fish advice
Options for fish advice-111915.docx

Here you go. Sorry you didn't get it. I need a new keyboard. I can't read any of the keys and I'm constantly mistyping n and m.

From: Larimer, Lisa
Sent: Thursday, November 19, 2015 11:07 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari Barash.Shari@epa.gov; John Wathem
Subject: Updated & shortened options for fish advice
Importance: High

Betsy-

It occurred to me this morning that since Joel has just recently gotten involved in the fish advice, he may not know that Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process

I took the information I pulled together for last week's meeting with Joel and made some changes:

- □□□□□□□ boiled it down to one page of clear options
- □□□□□□□ added a few things I mentioned verbally at last week's meeting like Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

- □□□□□□□ mentioned that state health departments sent comments and examples of their advisories Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process
- □□□□□□□ added an option that we could Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process

I'm not sure if you'll have time to look at it and get it to Joel before his meeting at 2:00 today, but I thought it was worth a shot.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Christensen, Christina[Christensen.Christina@epa.gov]
From: Larimer, Lisa
Sent: Tue 8/4/2015 7:41:59 PM
Subject: RE: Communications help for the fish advice guidance?

Thanks! I'll get back to you, probably next week, post-move. ☺

From: Christensen, Christina
Sent: Tuesday, August 04, 2015 3:13 PM
To: Larimer, Lisa
Subject: Communications help for the fish advice guidance?

Hi Lisa,

I just wanted to check in with you to see if Ambria and I can be of help in terms of the communications strategy for the fish advice guidance (which I understand will be released in the winter?).

Cara mentioned that the outreach we did in 2004 was very audience-driven (brochures geared towards Asian speaking women of child bearing age, Spanish speaking women of child bearing age, etc), and we will want our outreach in 2015 to be similarly audience-driven, but there may be differences in terms of updated demographics, target audiences, forms of outreach (podcasts, social media, interviews), etc. Also we may have a different slant on our outreach than FDA will have, and therefore may have some EPA-specific communications and outreach products.

Let me know if there is anything we can do to help – maybe a meeting with you, Cara, Jeff Bigler, Ambria and myself to come up with a plan? Happy to set that up if it would be useful.

Christina

To: Wood, Robert[Wood.Robert@epa.gov]
From: Larimer, Lisa
Sent: Fri 11/20/2015 2:32:32 PM
Subject: RE: Fish Advice

I could use a bagel to go with my coffee….. ☺ (kidding!)

From: Wood, Robert
Sent: Friday, November 20, 2015 9:31 AM
To: Behl, Betsy <Behl.Betsy@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Re: Fish Advice

Thanks. Let me know if you need me for anything.

Robert Wood

Director,

Engineering and Analysis Division

U.S. EPA Office of Water

202-566-1822

c) 202-329-8053

Sent from my iPhone (please excuse typos)

On Nov 20, 2015, at 9:23 AM, Behl, Betsy <Behl.Betsy@epa.gov> wrote:

> I am copying Rob, who is acting for Betsy today, in case you need signatures on anything.
>
> **From:** Southerland, Elizabeth
> **Sent:** Friday, November 20, 2015 7:24 AM
> **To:** Barash, Shari <Barash.Shari@epa.gov>

Cc: Behl, Betsy <Behl.Betsy@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Re: Fish Advice

No, transmit directly and just copy me. I am trapped with a lot of WERF work today including a 1 to 3 PM call. I don't want to hold you up.

Sent from my iPhone

On Nov 20, 2015, at 7:19 AM, Barash, Shari <Barash.Shari@epa.gov> wrote:

> Betsy,
>
> Lisa and I are working today and I think we can get something done today. Should we send to you to transmit to Joel?
>
> Shari
>
> Sent from my iPhone
>
> On Nov 20, 2015, at 6:51 AM, Southerland, Elizabeth <Southerland.Elizabeth@epa.gov> wrote:
>
> > Thanks, Joel, for helping us through this. I am copying the other fish advice team members because I don't know who is in the office today. Sara Hisel-McCoy is the DD involved, not Betsy Behl.
> >
> > Sent from my iPhone
> >
> > On Nov 19, 2015, at 9:28 PM, Beauvais, Joel <Beauvais.Joel@epa.gov> wrote:

Ex. 5 - Deliberative Process

Thanks for your help on this.

Joel

To: Bigler, Jeff[Bigler.Jeff@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 8/4/2015 7:23:49 PM
Subject: FW: Communications help for the fish advice guidance?

FYI

From: Christensen, Christina
Sent: Tuesday, August 04, 2015 3:13 PM
To: Larimer, Lisa
Subject: Communications help for the fish advice guidance?

Hi Lisa,

I just wanted to check in with you to see if Ambria and I can be of help in terms of the communications strategy for the fish advice guidance (which I understand will be released in the winter?).

Cara mentioned that the outreach we did in 2004 was very audience-driven (brochures geared towards Asian speaking women of child bearing age, Spanish speaking women of child bearing age, etc), and we will want our outreach in 2015 to be similarly audience-driven, but there may be differences in terms of updated demographics, target audiences, forms of outreach (podcasts, social media, interviews), etc. Also we may have a different slant on our outreach than FDA will have, and therefore may have some EPA-specific communications and outreach products.

Let me know if there is anything we can do to help – maybe a meeting with you, Cara, Jeff Bigler, Ambria and myself to come up with a plan? Happy to set that up if it would be useful.

Christina

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Fri 11/20/2015 2:27:09 PM
Subject: RE: Fish Advice

I love Google. I'm learning a lot about Ex. 5 - Deliberative Process What did we do before Google? (rhetorical question)

From: Barash, Shari
Sent: Friday, November 20, 2015 9:17 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Cc: Behl, Betsy <Behl.Betsy@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: Fish Advice

My only guess is that he means **Ex. 5 - Deliberative Process** **Ex. 5 - Deliberative Process** I will go google!

Shari Z. Barash

Acting Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Larimer, Lisa
Sent: Friday, November 20, 2015 9:15 AM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Cc: Barash, Shari <Barash.Shari@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Wathen, John <Wathen.John@epa.gov>

Subject: RE: Fish Advice

Any ideas on what Joel means by Ex. 5 - Deliberative Process

From: Hisel-Mccoy, Sara
Sent: Friday, November 20, 2015 8:55 AM
Cc: Barash, Shari <Barash.Shari@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Re: Fish Advice

Pls copy me as well. Thank you. Sara
Sara Hisel-McCoy

Standards and Health Protection Division

202 566-1649

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> > On Nov 20, 2015, at 6:51 AM, Southerland, Elizabeth <Southerland.Elizabeth@epa.gov> wrote:
> >
> > > Thanks, Joel, for helping us through this. I am copying the other fish advice team members because I don't know who is in the office today. Sara Hisel-McCoy is

the DD involved, not Betsy Behl.

Sent from my iPhone

On Nov 19, 2015, at 9:28 PM, Beauvais, Joel <Beauvais.Joel@epa.gov> wrote:

Ex. 5 - Deliberative Process

Thanks for your help on this.

Joel

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
From: Larimer, Lisa
Sent: Tue 8/4/2015 2:00:01 PM
Subject: RE: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

I'll work on it today and cc you.

From: Conerly, Octavia
Sent: Tuesday, August 04, 2015 8:16 AM
To: Bethel, Heidi
Cc: Larimer, Lisa
Subject: Re: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Usually the Division fills out the form.

Sent from my iPhone

On Aug 4, 2015, at 8:09 AM, Bethel, Heidi <Bethel.Heidi@epa.gov> wrote:

> Do you need the form?
>
> **From:** Conerly, Octavia
> **Sent:** Tuesday, August 04, 2015 8:09 AM
> **To:** Bethel, Heidi
> **Cc:** Larimer, Lisa; Klasen, Matthew; Naples, Eileen
> **Subject:** Re: Request for Admin meeting request form: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy
>
> Heidi,
>
> I am working from home today.
>
> Lisa, I am not sure if Jeanette is in the office today. So please make sure you include me when you send the invite forward. Thank you.
>
> Sent from my iPhone
>
> On Aug 4, 2015, at 8:03 AM, Bethel, Heidi <Bethel.Heidi@epa.gov> wrote:

Hi Octavia and Lisa,

Would the two of you please work on a meeting request form for the Fish Advice meeting with the Administrator? I have informed Matt and Eileen that this will be coming their way to schedule. Please let me know how I may help. Ken indicated that we should have the meeting with the Administrator in the next week or two.

Thanks,

Heidi

(202) 566-2054

From: Bethel, Heidi
Sent: Monday, August 03, 2015 3:43 PM
To: Naples, Eileen
Cc: Klasen, Matthew; Conerly, Octavia; Penman, Crystal
Subject: Meeting Request coming your way! Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Hi Eileen,

Our program office briefed Ken on the FDA/ EPA fish consumption advice this afternoon and Ken asked for a half hour briefing with the Administrator within a week or two time frame. It is timely, but not urgent. OW would like to release the advice in September we are possibly looking for an Administrator level announcement jointly with FDA. This issue was previously handled mostly at the Bob Sussman level. I can work with OST on a meeting request in the next day, but wanted to give you a heads up on this item.

Thanks,

Heidi

(202) 566-2054

Subject: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy

participant code Ex. 6 - Personal Privacy

Location: 3233 WJCE

Start: Mon 8/3/2015 1:00 PM

End: Mon 8/3/2015 1:30 PM

Recurrence: (none)

Meeting Status: Meeting organizer

Organizer: Kopocis, Ken

Required Attendees: Southerland, Elizabeth; Hisel-Mccoy, Sara; Larimer, Lisa; Bigler, Jeff; Wathen, John

Optional Attendees: Naidenko, Olga; Conerly, Octavia; Gilinsky, Ellen; Penman, Crystal; Fontenelle, Samantha

Poc Lisa Larimer 202-566-1017

<FISH_CHART_H_7.24.pdf>

<draft FR notice-fish advice.Version 1.docx>

<Briefing agenda.doc>

<FDA-EPA Fish Advice briefing.pptx>

<Joint FDA_EPA Fish Advice_07_13_2015.pdf>

To: Christensen, Christina[Christensen.Christina@epa.gov]; McDonald, Ambria[McDonald.Ambria@epa.gov]
From: Larimer, Lisa
Sent: Tue 9/22/2015 8:38:39 PM
Subject: Notes from our meeting yesterday on fish advice

Sorry if my sending this list wasn't timely enough for your meeting with Cara. Looks like the release might be delayed a bit, judging by this morning's briefing. (sigh)

MATERIALS:

External materials

•□□□□□□ The advice: Infographic/chart showing fish by category (horizontal & vertical format versions) and accompanying Q&A [DONE]

•□□□□□□ Summary of comments and agencies' responses [DONE]

•□□□□□□ Updated web pages [TO DO – Ambria to send me access to current pages]

•□□□□□□ Notice in *Federal Register* [DONE]

•□□□□□□ Joint press release announcing the advice [TO DO – assuming EPA & FDA comm people are doing this]

•□□□□□□ Joint media advisory, if we do a media call to announce it, as we did last year [TO DO – assuming EPA & FDA comm people are doing this]

•□□□□□□ Consumer update (FDA)

•□□□□□□ Email via Water Headlines (EPA) [TO DO – Ambria]

•□□□□□□ Social media posts [TO DO – Ambria]

•□□□□□□ Stakeholder notification [DON'T KNOW WHAT COMM PEOPLE HAVE IN MIND]

•□□□□□□ Congressional notification [DON'T KNOW WHAT COMM PEOPLE HAVE IN MIND]

Internal materials

- Key messages and Q&A for press offices [DONE]
- Talking points for FDA and EPA spokespeople on media call [TO DO]

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Klasen, Matthew[Klasen.Matthew@epa.gov]
From: Larimer, Lisa
Sent: Mon 9/21/2015 8:11:13 PM
Subject: RE: Materials for fish advice briefing with DA at 11:00 tomorrow

Thanks, Matt. Since a few people were clamoring, I sent them out to folks up to the DD/OD level in case your folks are busy for a while.

-Lisa

From: Klasen, Matthew
Sent: Monday, September 21, 2015 4:04 PM
To: Larimer, Lisa
Subject: RE: Materials for fish advice briefing with DA at 11:00 tomorrow

Hey Lisa – good idea. Whether or not we attach the docs to the meeting invites is mostly a case-by-case decision. I just sent a note to get them added, so that should happen shortly. (It certainly makes sense with the diverse group of folks on the meeting invite.)

Thanks,
Matt

From: Larimer, Lisa
Sent: Monday, September 21, 2015 4:00 PM
To: Klasen, Matthew
Subject: Materials for fish advice briefing with DA at 11:00 tomorrow

Hi Matt,

Sorry to bother you, but folks have been asking me for the briefing materials since they are not attached to the meeting invitation. Is there a reason they are not attached? If so, I'm happy to send them out.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Larimer, Lisa
Sent: Thur 11/19/2015 5:00:05 PM
Subject: RE: Updated & shortened options for fish advice

Thanks; sorry, I didn't realize you were out on sick leave today. Stop checking email! ☺

From: Southerland, Elizabeth
Sent: Thursday, November 19, 2015 11:56 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: Re: Updated & shortened options for fish advice

Great job! I sent to Joel and Heidi Bethel.

Sent from my iPhone

On Nov 19, 2015, at 11:07 AM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

Betsy-

It occurred to me this morning that since Joel has just recently gotten involved in the fish advice, he may not know that Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

I took the information I pulled together for last week's meeting with Joel and made some changes:

- □□□□□□□ boiled it down to one page of clear options
- □□□□□□□ added a few things I mentioned verbally at last week's meeting like Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

- □□□□□□□ mentioned that state health departments sent comments and examples of their advisories Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

•□□□□□□ added an option that we could Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

I'm not sure if you'll have time to look at it and get it to Joel before his meeting at 2:00 today, but I thought it was worth a shot.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

<Options for fish advice-111915.docx>

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Fri 7/17/2015 8:53:54 PM
Subject: Newest comment response document
Responses to comments-071715.docx

Nope, the comment response table is old too. Here's the latest – I changed the date to today so you know it's current. See separate email for updated FR notice.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Friday, July 17, 2015 3:42 PM
To: Larimer, Lisa
Subject: RE: Commissioner briefing SOP.doc

Hi Lisa,

I've included some other things to ensure I've got the right versions to send forward. Please confirm they are correct. Thanks for sending the QA.

Sharon

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Friday, July 17, 2015 3:02 PM
To: Natanblut, Sharon
Subject: RE: Commissioner briefing SOP.doc

Thanks. When you get a chance, please send the advice. It turns out we needs to brief a few other offices before the AA on July 30, so it would be great to have the latest version (even if it's not quite the final one).

We are meeting with communication folks next week, so if you could share your draft comm plan, that would be greatly appreciated also.

Thanks!

Lisa

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Friday, July 17, 2015 12:36 PM
To: Larimer, Lisa
Subject: Commissioner briefing SOP.doc

Hi Lisa,

I'm just finishing getting all the links to this and then will send that forward. Around 2 pm I hope to start working on the PPT, which will follow the agenda. Does that help at all?

Sharon

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Fri 7/17/2015 8:42:13 PM
Subject: RE: can you send me a word version of the FR notice (so people can review/add edits or comments? thx
draft FR notice-fish advice-062515.docx

At first I was confused, because you just sent me a Word version. Then I saw it was an older version. I looked at the one in the shared folder and it needed edits accepted, etc. I've done that and included it here. Do you need anything else before I take off for the weekend?

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Friday, July 17, 2015 3:48 PM
To: Larimer, Lisa
Subject: can you send me a word version of the FR notice (so people can review/add edits or comments? thx
Importance: High

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Friday, July 17, 2015 2:56 PM
To: Natanblut, Sharon
Subject: RE: version control! would you send most recent set of Supplemental QAs?

The one on OneDrive is the most recent version. Here's a copy of it. Same as I sent you July 9, by the way.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Friday, July 17, 2015 12:40 PM
To: Larimer, Lisa
Subject: version control! would you send most recent set of Supplemental QAs?
Importance: High

To: Berger, Martha[Berger.Martha@epa.gov]
From: Larimer, Lisa
Sent: Fri 7/17/2015 3:57:09 PM
Subject: Would like to update someone in CHPO on EPA-FDA fish advisory progress

Hi Martha,

This is a bit of a shot in the dark because I'm relatively new to the fish advice work and I'm not sure who, if anyone, our office has contacted in the past about this. The workgroup has reviewed comments from the public on the 2014 draft version of the fish advisory for pregnant women and children and has almost finalized everything. We received comments from the Children's Health Protection Advisory Committee, and I found your name associated with that committee. We are not looking to meet with CHPAC itself but would like to meet with someone, probably at the staff level, in the Children's Health Protection Office to let them know what the final version of the advice is likely to look like and how we addressed CHPAC's comments.

If you could let me know if you are the correct person, or if not then who is, and I'd be happy to set up a meeting with my team. We'd like to do it before we brief our AA on July 30.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Thur 7/9/2015 9:18:02 PM
Subject: RE: separate domain for seafood advice
draft FR notice-fish advice-062515.docx
Responses to comments-070915.docx
Fish Advice Qs and As-070915.docx

Here you go! It seems people came to agreement with that last Q&A, so I added it in.

-Lisa

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Wednesday, July 08, 2015 5:55 PM
To: Larimer, Lisa
Subject: RE: separate domain for seafood advice

Thanks. Lisa, could you please send to me the latest versions of the FR notice, the comment summary, etc?

Sharon

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, July 08, 2015 4:17 PM
To: Natanblut, Sharon
Subject: RE: separate domain for seafood advice

Yes.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, July 07, 2015 12:53 PM
To: Larimer, Lisa
Subject: RE: separate domain for seafood advice

Makes sense. So we should put both of them on our chart?

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, July 07, 2015 12:38 PM
To: Natanblut, Sharon
Subject: RE: separate domain for seafood advice

That's too bad. I think a second choice would be for us to do twin sites: www.fda.gov/fishadvice and www.epa.gov/fishadvice - I'm pretty sure I can get that through pretty easily on our end.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, July 07, 2015 8:51 AM
To: Larimer, Lisa
Subject: FW: separate domain for seafood advice

Please see below regarding establishing a URL. Still checking on things.

From: Das, Sharmi
Sent: Monday, July 06, 2015 3:34 PM
To: Natanblut, Sharon
Cc: Herndon, Michael L
Subject: separate domain for seafood advice

Hi Sharon, Mike and I talked with Chris Mulieri today about establishing a second level domain (like hhs.gov) for EPA/FDA seafood guidance. Here's what we discussed:

1. There's a moratorium on .gov sites. The last HHS web council meeting confirmed that the moratorium is still in place.
2. Only way we can get permission to do is justify with strong reasons for a separate domain. The request must be approved by head of ASPA and HHS CIO. CTP did one a few years back BeTobaccoFree.gov http://betobaccofree.hhs.gov/index.html , it's a full-blown site with lots of content and social media campaign, etc.
3. Problems to consider with establishing a separate URL at this time is that people are already used to going to FDA or EPA websites for draft guidance on seafood, therefore

search engine optimization will be lost. Content must be robust in order to stand up a separate domain and attract people to this new site.

4. A catchy alias like "seafoodadvice from FDAEPA" may be an alternative.

Mike and I are happy to chat with you more about this. Let us know if you have any questions. Thanks.

s.

To: Jones, William[William.Jones@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 5/12/2015 5:05:53 PM
Subject: RE: 4th FDA-EPA meeting on fish advice

Ex. 5 - Deliberative Process

Thanks, Bill.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Tuesday, May 12, 2015 11:15 AM
To: Larimer, Lisa; Natanblut, Sharon; Bigler, Jeff; Smegal, Deborah; Wathen, John
Subject: RE: 4th FDA-EPA meeting on fish advice

Ex. 5 - Deliberative Process

From: Jones, William
Sent: Tuesday, May 12, 2015 9:41 AM
To: 'Larimer, Lisa'; Natanblut, Sharon; Bigler, Jeff; Smegal, Deborah; Wathen, John
Subject: RE: 4th FDA-EPA meeting on fish advice

Agenda looks good, and I can still be your contact. We have a small cafeteria in our building, which works if you just want some kind of a sandwich. Some people get lunch there every day; I generally brownbag. Anything else is a 15 minute walk and not much better. I do recommend that we break at 11:50 for those who want to get something at the cafeteria…at noon or shortly thereafter you can be in line for 10 minutes sometimes.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, May 12, 2015 9:34 AM

To: Natanblut, Sharon; Jones, William; Bigler, Jeff; Smegal, Deborah; Elkin, Ted; Wathen, John
Subject: RE: 4th FDA-EPA meeting on fish advice

I believe the draft agenda I sent yesterday (let me know if it did not go out!) had 12-1 for lunch. It also had some questions for you FDA folks, such as is Bill the person we should contact at the front desk (I still have his numbers), and are there places to eat nearby or should we brownbag it?

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, May 11, 2015 7:52 PM
To: Jones, William; Larimer, Lisa; Bigler, Jeff; Smegal, Deborah; Elkin, Ted; Wathen, John
Subject: RE: 4th FDA-EPA meeting on fish advice

Thanks.

From: Jones, William
Sent: Monday, May 11, 2015 6:47 PM
To: Natanblut, Sharon; Larimer.Lisa@epa.gov; Bigler.Jeff@epa.gov; Smegal, Deborah; Elkin, Ted; Wathen.John@epa.gov
Subject: Re: 4th FDA-EPA meeting on fish advice

That sounds good to me.

From: Natanblut, Sharon
Sent: Monday, May 11, 2015 06:15 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Bigler, Jeff <Bigler.Jeff@epa.gov>; Jones, William; Smegal, Deborah; Elkin, Ted; Wathen, John <Wathen.John@epa.gov>
Subject: RE: 4th FDA-EPA meeting on fish advice

Hi there,

Turns out I have an HHS conference call between 12 and 12:30 on Wednesday. Would you mind if we scheduled that time for lunch?

Thanks.

Sharon

-----Original Appointment-----
From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, April 16, 2015 10:45 AM
To: Larimer, Lisa; Bigler, Jeff; Jones, William; Smegal, Deborah; Natanblut, Sharon; Elkin, Ted; Wathen, John
Subject: 4th FDA-EPA meeting on fish advice
When: Wednesday, May 13, 2015 9:00 AM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: CFSAN CP Room 2E-032

Main topic: Tackle the response to comments

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
Cc: McRae, Evelyn[McRae.Evelyn@epa.gov]
From: Larimer, Lisa
Sent: Wed 9/16/2015 4:05:57 PM
Subject: RE: REMINDER: FDA-EPA Fish Advice

Yes, I am waiting to hear if Sara has reviewed it yet.

From: Conerly, Octavia
Sent: Wednesday, September 16, 2015 11:24 AM
To: Larimer, Lisa
Cc: McRae, Evelyn
Subject: REMINDER: FDA-EPA Fish Advice

Good morning Lisa,
Just a friendly reminder that your briefing document is due to Betsy today by 3pm. Thanks in advance!

Subject:	FDA-EPA Fish Advice
Location:	DCRoomARN3530CFTB/DC-Ariel-Rios-AO
Start:	Tue 9/22/2015 11:00 AM
End:	Tue 9/22/2015 11:45 AM
Recurrence:	(none)
Meeting Status:	Accepted
Organizer:	Meiburg, Stan
Required Attendees:	Larimer, Lisa; Wathen, John; Hisel-Mccoy, Sara; Southerland, Elizabeth; Kopocis, Ken; Gilinsky, Ellen; Burke, Thomas; Etzel, Ruth; Coopwood, Theodore; Mitchell, Stacey; Schroer, Lee; Klasen, Matthew; Ingram, Amir
Optional Attendees:	Loop, Travis; Lalley, Cara; Kavlock, Robert; Hauchman, Fred; Schoeny, Rita; Reed, Khesha; Firestone, Michael; Penman, Crystal; Gentry, Nathan; Foos, Brenda; Conerly, Octavia

Point of Contact for the Meeting: Lisa Larimer 566-1017
SCt: Denise Anderson, 564-1782

Ex. 6 - Personal Privacy

Purpose: Share the final joint FDA-EPA fish advice with EPA senior leadership. HHS senior leadership is receiving a comparable briefing. The workgroup's goal is to announce

	the advice in September/October 2015, contingent upon timing of review by HHS and OMB.
Background:	An FDA-EPA workgroup has developed an update to the March 2004 fish advisory on mercury in fish and shellfish. The advice recommends consumption frequencies for the target audience of pregnant and breastfeeding women, women who could become pregnant, and children.
Last possible date for the meeting:	After 9/9/15 and before 9/25/15
EPA Staff (Required):	OW: Lisa Larimer, John Wathen, Sara Hisel-McCoy, Elizabeth Southerland, Ken Kopocis, Ellen Gilinsky ORD: Thomas Burke OA: Ruth Etzel, Theodore Coopwood OGC: Stacey Mitchell, Lee Schroer
EPA Staff (Optional):	OW: Travis Loop, Cara Lalley ORD: Robert Kavlock, Fred Hauchman, Rita Schoeny OA: Khesha Reed, Michael Firestone

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 7/8/2015 8:16:40 PM
Subject: RE: separate domain for seafood advice

Yes.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, July 07, 2015 12:53 PM
To: Larimer, Lisa
Subject: RE: separate domain for seafood advice

Makes sense. So we should put both of them on our chart?

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, July 07, 2015 12:38 PM
To: Natanblut, Sharon
Subject: RE: separate domain for seafood advice

That's too bad. I think a second choice would be for us to do twin sites: www.fda.gov/fishadvice and www.epa.gov/fishadvice - I'm pretty sure I can get that through pretty easily on our end.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, July 07, 2015 8:51 AM
To: Larimer, Lisa
Subject: FW: separate domain for seafood advice

Please see below regarding establishing a URL. Still checking on things.

From: Das, Sharmi
Sent: Monday, July 06, 2015 3:34 PM
To: Natanblut, Sharon
Cc: Herndon, Michael L

Subject: separate domain for seafood advice

Hi Sharon, Mike and I talked with Chris Mulieri today about establishing a second level domain (like hhs.gov) for EPA/FDA seafood guidance. Here's what we discussed:

1. There's a moratorium on .gov sites. The last HHS web council meeting confirmed that the moratorium is still in place.
2. Only way we can get permission to do is justify with strong reasons for a separate domain. The request must be approved by head of ASPA and HHS CIO. CTP did one a few years back BeTobaccoFree.gov http://betobaccofree.hhs.gov/index.html , it's a full-blown site with lots of content and social media campaign, etc.
3. Problems to consider with establishing a separate URL at this time is that people are already used to going to FDA or EPA websites for draft guidance on seafood, therefore search engine optimization will be lost. Content must be robust in order to stand up a separate domain and attract people to this new site.
4. A catchy alias like "seafoodadvice from FDAEPA" may be an alternative.

Mike and I are happy to chat with you more about this. Let us know if you have any questions. Thanks.

s.

To: Wathen, John[Wathen.John@epa.gov]; Robiou, Grace[Robiou.Grace@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Larimer, Lisa
Sent: Tue 4/7/2015 8:10:10 PM
Subject: RE: Proposed Agenda for 2nd Meeting with FDA

I'm trying to get a revised/more concise table together showing Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process I think I'm almost there. When I have it done, I will send that file, the newest comment summary document, and the draft agenda to everyone.

From: Wathen, John
Sent: Tuesday, April 07, 2015 3:22 PM
To: Robiou, Grace; Larimer, Lisa; Bigler, Jeff
Subject: RE: Proposed Agenda for 2nd Meeting with FDA

Looks very good, but I added an "f." to the chart discussion.

~John

From: Robiou, Grace
Sent: Tuesday, April 07, 2015 2:42 PM
To: Larimer, Lisa; Bigler, Jeff; Wathen, John
Subject: Proposed Agenda for 2nd Meeting with FDA

Here is a proposed agenda. Please provide Lisa with your thoughts/comments. She will be sending out the final agenda to FDA.

Lisa – I am thinking we should provide this proposed agenda tomorrow, Wed, or Thursday for FDA folks to react to?

Proposed Agenda

Tuesday, April 14

Second FDA-EPA Meeting on Advice for Mercury Concentrations in Fish

9:00-9:15 Welcome and Review of Today's Agenda (Grace)

9:15 – 9:30 Verbal Summary of Public Comments that came in at end of Comment period (Westat)

[Handout #1: Final Summary of Comments document (not for public release)]

9:30 – 10:30 Fish Chart (Lisa)

Handout #2: Chart, Version dated XX/YY/ZZ

Discussion Topics:

a.

b.
da

c.

d.

e.

f.
pe

Ex. 5 - Deliberative Process

10:30 – 10:45 Break

10:45 – 11:30 Fish Chart, continuation

11:30 – 12:15 Chart Mock ups (Sharon)

Handout #3: Design options

12:15 – 1:15 Lunch

1:15 – 2:45 Revisions to Final Advice (Sharon)

Handout #4: Red-line strike out

2:45 – 3:00 Break

3:00 – 4:00 Qs and As (Sharon)

Handout #5: Annotated Qs and As Ex. 5 - Deliberative Process

4:00 Next Steps

Handout #6: Table for Response of Comments (for public release)

To: Wathen, John[Wathen.John@epa.gov]; Schroer, Lee[schroer.lee@epa.gov]
From: Larimer, Lisa
Sent: Sun 8/2/2015 3:59:03 PM
Subject: Re: FDA-EPA fish advice files

John,

Those were attached as well. You had to scroll down to see all the attachments.

-Lisa

From: Wathen, John
Sent: Friday, July 31, 2015 4:49 PM
To: Larimer, Lisa; Schroer, Lee
Subject: Re: FDA-EPA fish advice files

Lisa, Lee-

Should Lee cast his perspicacious eyes on our response to comments document as well?

~John

From: Larimer, Lisa
Sent: Friday, July 31, 2015 2:48 PM
To: Schroer, Lee
Cc: Wathen, John
Subject: FDA-EPA fish advice files

Hi Lee,

Shari said she talked to you and that you were willing to look over our materials related to the updated FDA-EPA fish advice. Apparently FDA's OGC has suggested additions to the FR notice - something to do with the Data Quality Act - so that one's not quite final. But we are hoping the rest are. Let me know if you see anything problematic from a legal standpoint. Just so you know, practically every word down to the comma placement has been negotiated with FDA. You may notice the tone is conversational and not super scientific; that was intentional.

We are briefing Ken on Monday afternoon. It would be great if you could look these over by then, but not expected since we didn't send them until Friday afternoon. If Ken asks, we can always say that OGC is in the process of reviewing them.

Thanks! And have a great weekend,

Lisa

From: Larimer, Lisa
Location: DCRoomARN3530CFTB/DC-Ariel-Rios-AO
Importance: Normal
Subject: FW: FDA-EPA Fish Advice
Start Date/Time: Tue 9/22/2015 3:00:00 PM
End Date/Time: Tue 9/22/2015 3:45:00 PM
Briefing Memo FDA-EPA fish advice.docx

-----Original Appointment-----
From: Meiburg, Stan
Sent: Thursday, September 10, 2015 10:21 AM
To: Meiburg, Stan; Larimer, Lisa; Wathen, John; Hisel-Mccoy, Sara; Southerland, Elizabeth; Kopocis, Ken; Gilinsky, Ellen; Burke, Thomas; Etzel, Ruth; Coopwood, Theodore; Mitchell, Stacey; Schroer, Lee; Klasen, Matthew; Ingram, Amir
Cc: Loop, Travis; Lalley, Cara; Kavlock, Robert; Hauchman, Fred; Schoeny, Rita; Reed, Khesha; Firestone, Michael; Penman, Crystal; Gentry, Nathan; Foos, Brenda; Conerly, Octavia
Subject: FDA-EPA Fish Advice
When: Tuesday, September 22, 2015 11:00 AM-11:45 AM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomARN3530CFTB/DC-Ariel-Rios-AO

Point of Contact for the Meeting: Lisa Larimer 566-1017
SCt: Denise Anderson, 564-1782

Ex. 6 - Personal Privacy

Purpose:	Share the final joint FDA-EPA fish advice with EPA senior leadership. HHS senior leadership is receiving a comparable briefing. The workgroup's goal is to announce the advice in September/October 2015, contingent upon timing of review by HHS and OMB.
Background:	An FDA-EPA workgroup has developed an update to the March 2004 fish advisory on mercury in fish and shellfish. The advice recommends consumption frequencies for the target audience of pregnant and breastfeeding women, women who could become pregnant, and children.
Last possible date for the meeting:	After 9/9/15 and before 9/25/15
EPA Staff (Required):	OW: Lisa Larimer, John Wathen, Sara Hisel-McCoy, Elizabeth Southerland, Ken Kopocis, Ellen Gilinsky ORD: Thomas Burke OA: Ruth Etzel, Theodore Coopwood OGC: Stacey Mitchell, Lee Schroer

EPA Staff (Optional):	OW: Travis Loop, Cara Lalley ORD: Robert Kavlock, Fred Hauchman, Rita Schoeny OA: Khesha Reed, Michael Firestone

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: Larimer, Lisa
Sent: Mon 9/21/2015 7:38:27 PM
Subject: RE: fish advice (horizontal & vertical charts and Q&A)

Did you say you were able to pull a copy of the powerpoint off the meeting invite? I ask because I don't see it and will send out if it's not there.

From: Reed, Khesha
Sent: Monday, September 21, 2015 3:38 PM
To: Larimer, Lisa
Subject: Re: fish advice (horizontal & vertical charts and Q&A)

Thanks!

Sent from my iPhone

On Sep 21, 2015, at 3:30 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

> Khesha-
>
> We just had some email back and forth with FDA today on Q&A [redacted] so the wording of that one may change slightly (essentially changing Ex. 5 - Deliberative Process and Ex. 5 - Deliberative Process), but unless changes result from HHS' meeting today with the Secretary or our meeting tomorrow with the Deputy Administrator, we think these are essentially final.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

<FISH_CHART_V_9.2.pdf>

<FISH_CHART_H_9.2.pdf>

<Fish Advice Qs and As-8 24 15 clean with comment box for NIH and placeholder for diagram.docx>

To: rich. Ex. 6 - Personal Privacy
From: Larimer, Lisa
Sent: Wed 1/18/2017 2:51:10 PM
Subject: The fish advice has been released!

Press release: https://www.epa.gov/newsreleases/epa-and-fda-issue-final-fish-consumption-advice-0

(Annoyingly, the press release only links to FDA's page and doesn't even use the easy to remember fda.gov/fishadvice and epa.gov/fishadvice link we created!)

For a snazzier look and feel for the advice materials, go to fda.gov/fishadvice

For more comprehensive information about fish and shellfish in general, go to epa.gov/fishadvice

EPA's direct link to the EPA-FDA fish advice is https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

Cc: Wathen, John[Wathen.John@epa.gov]
To: Schroer, Lee[schroer.lee@epa.gov]
From: Larimer, Lisa
Sent: Fri 7/31/2015 6:48:36 PM
Subject: FDA-EPA fish advice files
draft FR notice-fish advice.Version 1.docx
Fish Advice Qs and As-072915.docx
FISH_CHART_H_7.24.pdf
FISH_CHART_V_7.24.pdf
Responses to comments-072315.docx
technical web page-fish advice-072315.docx

Hi Lee,

Shari said she talked to you and that you were willing to look over our materials related to the updated FDA-EPA fish advice. Apparently FDA's OGC has suggested additions to the FR notice - something to do with the Data Quality Act - so that one's not quite final. But we are hoping the rest are. Let me know if you see anything problematic from a legal standpoint. Just so you know, practically every word down to the comma placement has been negotiated with FDA. You may notice the tone is conversational and not super scientific; that was intentional.

We are briefing Ken on Monday afternoon. It would be great if you could look these over by then, but not expected since we didn't send them until Friday afternoon. If Ken asks, we can always say that OGC is in the process of reviewing them.

Thanks! And have a great weekend,

Lisa

To: schroer, lee[schroer.lee@epa.gov]
From: Larimer, Lisa
Sent: Wed 9/16/2015 1:30:57 PM
Subject: Fish advice materials
FISH_CHART_V_9.2.pdf
FISH_CHART_H_9.2.pdf
FRDTS 2015-646-draft FR notice-fish consumption advice revised version 8 24 2015 clean.docx

Hi Lee,

I'm rushing off to a meeting, but should be able to check in again before your 11:00 if I'm missing something.

I believe you asked only for the Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Let me know if you need anything else (Q&A, etc).

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Bigler, Jeff[Bigler.Jeff@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Fri 2/13/2015 4:10:06 PM
Subject: FW: HOLD: FIRST IN-PERSON MEETING OF FDA-EPA on FISH ADVISORY
removed.txt

Did either of you successfully get the file? If not, I'll ask him to rename the extension and resend.

-Lisa

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Thursday, February 12, 2015 12:52 PM
To: Smegal, Deborah; Wathen, John; Carrington, Clark D; 'Deborah.smegal@fda.hhs.gov'; Bigler, Jeff; Larimer, Lisa; Natanblut, Sharon
Cc: Elkin, Ted
Subject: RE: HOLD: FIRST IN-PERSON MEETING OF FDA-EPA on FISH ADVISORY

March 17th now works for me as well and attached is the zip file of comments I just received from Dockets Management.

From: Smegal, Deborah
Sent: Thursday, February 12, 2015 12:13 PM
To: Wathen, John; Carrington, Clark D; Natanblut, Sharon; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; Elkin, Ted; Bigler, Jeff; Larimer, Lisa
Subject: RE: HOLD: FIRST IN-PERSON MEETING OF FDA-EPA on FISH ADVISORY

HI,

March 17th works for both Clark and me.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Thursday, February 12, 2015 10:41 AM
To: Carrington, Clark D; Natanblut, Sharon; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; Elkin, Ted; Bigler, Jeff; Wathen, John; Larimer, Lisa
Cc: Smegal, Deborah
Subject: HOLD: FIRST IN-PERSON MEETING OF FDA-EPA on FISH ADVISORY

Folks-

The pitfall associated with setting up a meeting without actually consulting one's calendar has befallen me, and I have a conflict on our proposed March 9 meeting date. While looking further at the calendar, I note that it is a very busy week for me, Grace and Lisa have an important meeting Wed., and I recall constraints on FDA folks' part as well with travel and other factors for the week of March 9. Revisiting this in the light of my pitfall, the following week- that of March 16- looks much better for us, and I am inquiring how it looks for our FDA team.

In looking at that week, I would like to propose Tues March 17, and as with the nixed March 9 date, suggest that we pretty much block out the whole day, so plan on 9:00-3:00, with logistical details to be worked out. Please let me know if this works, or propose another day that week.

Thanks very much, and apologies for needing a re-opener.

~John

John Wathen, Acting Chief

Fish, Shellfish, Beaches, & Outreach Branch (4305 T)

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Standards and Health Protection Division

Office of Science and Technology

Office of Water

US Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, DC 20460

202-566-0367 phone

202-566-0409 fax

http://www.epa.gov/waterscience

To: Martinez, Menchu[martinez.menchu-c@epa.gov]
From: Larimer, Lisa
Sent: Wed 7/8/2015 8:02:33 PM
Subject: RE: FDA-EPA fish advice schedule

Yes. She knows it though, so not sure you need to include it this time around.

From: Martinez, Menchu
Sent: Wednesday, July 08, 2015 3:14 PM
To: Larimer, Lisa
Subject: RE: FDA-EPA fish advice schedule

Is this still current? If so, I will include it in SHM's biweekly with Betsy. Thanks.

From: Larimer, Lisa
Sent: Monday, July 06, 2015 1:14 PM
To: Martinez, Menchu
Subject: FDA-EPA fish advice schedule

•□□□□□□ Week of July 13: Send entire package to EPA OST Director Betsy Southerland, FDA CFSAN Director Dr. Susan Mayne, and FDA Deputy Commissioner Mike Taylor.

•□□□□□□ Week of July 20: Brief the people listed above. [Betsy S said she does NOT need a briefing.]

•□□□□□□ Week of July 27: Send materials to and brief EPA Deputy Assistant Administrator Ken Kopocis and FDA Acting Commissioner Dr. Stephen Ostroff

•□□□□□□ August: EPA Administrator Gina McCarthy (if needed) and HHS Secretary Sylvia Burwell, then OMB

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Larimer, Lisa
Location: 5233A WJC-W
Importance: Normal
Subject: FW: Next steps on FDA-EPA Fish Advisory
Start Date/Time: Wed 1/28/2015 2:00:00 PM
End Date/Time: Wed 1/28/2015 2:30:00 PM

-----Original Appointment-----
From: McRae, Evelyn **On Behalf Of** Hisel-Mccoy, Sara
Sent: Friday, January 23, 2015 3:49 PM
To: Hisel-Mccoy, Sara; Southerland, Elizabeth; Wathen, John; sharon.natanblut@fda.hhs.gov; ted.elkin@fda.hhs.gov; Grace Robiou
Cc: Skane, Elizabeth; Lape, Jeff; Bigler, Jeff
Subject: Next steps on FDA-EPA Fish Advisory
When: Wednesday, January 28, 2015 9:00 AM-9:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: 5233A WJC-W

Conference Number: Ex. 6 - Personal Privacy

Conference Passcode: Ex. 6 - Personal Privacy

POC: John Wathen: 202 566 0367

To: Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Larimer, Lisa
Sent: Wed 7/8/2015 4:43:06 PM
Subject: SOLICITING INPUT: dual websites for seafood advice

We can't get a .gov website for our fish advice. It seems to makes sense for each agency then to have a website for this. We want our website to be listed on the chart too, yes? Or would that be confusing to the public?

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, July 07, 2015 12:53 PM
To: Larimer, Lisa
Subject: RE: separate domain for seafood advice

Makes sense. So we should put both of them on our chart?

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, July 07, 2015 12:38 PM
To: Natanblut, Sharon
Subject: RE: separate domain for seafood advice

That's too bad. I think a second choice would be for us to do twin sites: www.fda.gov/fishadvice and www.epa.gov/fishadvice - I'm pretty sure I can get that through pretty easily on our end.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, July 07, 2015 8:51 AM
To: Larimer, Lisa
Subject: FW: separate domain for seafood advice

Please see below regarding establishing a URL. Still checking on things.

From: Das, Sharmi
Sent: Monday, July 06, 2015 3:34 PM

To: Natanblut, Sharon
Cc: Herndon, Michael L
Subject: separate domain for seafood advice

Hi Sharon, Mike and I talked with Chris Mulieri today about establishing a second level domain (like hhs.gov) for EPA/FDA seafood guidance. Here's what we discussed:

1. There's a moratorium on .gov sites. The last HHS web council meeting confirmed that the moratorium is still in place.
2. Only way we can get permission to do is justify with strong reasons for a separate domain. The request must be approved by head of ASPA and HHS CIO. CTP did one a few years back BeTobaccoFree.gov http://betobaccofree.hhs.gov/index.html , it's a full-blown site with lots of content and social media campaign, etc.
3. Problems to consider with establishing a separate URL at this time is that people are already used to going to FDA or EPA websites for draft guidance on seafood, therefore search engine optimization will be lost. Content must be robust in order to stand up a separate domain and attract people to this new site.
4. A catchy alias like "seafoodadvice from FDAEPA" may be an alternative.

Mike and I are happy to chat with you more about this. Let us know if you have any questions. Thanks.

s.

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Wed 7/8/2015 4:21:57 PM
Subject: FW: My alternative for the question on what to do if you're not pregnant...

You and Jeff are on similar pages…

From: Bigler, Jeff
Sent: Tuesday, July 07, 2015 6:00 PM
To: Larimer, Lisa
Subject: Fwd: My alternative for the question on what to do if you're not pregnant...

Ex. 5 - Deliberative Process

□□□□□

Begin forwarded message:

From: "Natanblut, Sharon" <Sharon.Natanblut@fda.hhs.gov>
Date: July 7, 2015 at 2:48:59 PM EDT
To: "Fontenelle, Samantha" <Fontenelle.Samantha@epa.gov>, "Larimer, Lisa" <Larimer.Lisa@epa.gov>, "Jones, William" <William.Jones@fda.hhs.gov>, "Smegal, Deborah" <Deborah.Smegal@fda.hhs.gov>, "Bigler, Jeff" <Bigler.Jeff@epa.gov>, "Wathen, John" <Wathen.John@epa.gov>, "Naidenko, Olga" <Naidenko.Olga@epa.gov>
Subject: My alternative for the question on what to do if you're not pregnant...

Ex. 5 - Deliberative Process

From: Fontenelle, Samantha [mailto:Fontenelle.Samantha@epa.gov]
Sent: Tuesday, July 07, 2015 11:33 AM
To: Larimer, Lisa; Jones, William; Smegal, Deborah; Natanblut, Sharon; Bigler, Jeff; Wathen, John; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

I think "could" should be "would" in the final sentence.

From: Larimer, Lisa
Sent: Monday, July 06, 2015 2:47 PM
To: Jones, William; Smegal, Deborah; Fontenelle, Samantha; Natanblut, Sharon; Bigler, Jeff; Wathen, John; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

OK everyone, I went through everyone's email again to make sure I caught everything. If we can't resolve this soon, I propose we schedule a quick call. Talking it out will be faster than email.

Ex. 5 - Deliberative Process

Notes:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

-Lisa

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 5/5/2015 8:45:53 PM
Subject: FW: Draft of fish advice after 3rd FDA-EPA meeting (4/22/15)
draft Qs and A's 4.22.15.docx

Here it is

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Wednesday, April 22, 2015 6:25 PM
To: Larimer, Lisa; Natanblut, Sharon; Jones, William; Bigler, Jeff; Wathen, John
Subject: RE: Draft of fish advice after 3rd FDA-EPA meeting (4/22/15)

Hi,

Here is the latest draft of the Q's and A's. I added a few suggested edits to the EPA responses, but Sharon and Bill also need to weigh in.

I would prefer we hold the next meeting at FDA and would be happy to reserve a room.

Regards,

Debbie

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, April 22, 2015 2:38 PM
To: Natanblut, Sharon; Jones, William; Smegal, Deborah; Bigler, Jeff; Wathen, John
Subject: Draft of fish advice after 3rd FDA-EPA meeting (4/22/15)

Hi everyone,

Here is the version of the fish advice we developed this morning, and the final agenda in case anyone needs it for official records.

Lisa Larimer, P.E.

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Conerly, Octavia[Conerly.Octavia@epa.gov]; Penman, Crystal[Penman.Crystal@epa.gov]; Edwards, Crystal[Edwards.Crystal@epa.gov]
Cc: Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Larimer, Lisa
Sent: Wed 7/29/2015 5:57:55 PM
Subject: RE: Joint FDA/EPA Fish Advice call in 855-564-1700 ext 1104465 participant code 234567
Briefing agenda.doc

Sorry, slight change to agenda because Sara Hisel-McCoy won't be here tomorrow.

From: Conerly, Octavia
Sent: Wednesday, July 29, 2015 1:54 PM
To: Penman, Crystal; Edwards, Crystal
Cc: Bethel, Heidi; Larimer, Lisa
Subject: Joint FDA/EPA Fish Advice call in Ex. 6 - Personal Privacy ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Good afternoon Ladies,

I have attached the briefing materials for the aforementioned meeting on tomorrow. I will bring 3 copies down also. If you have any questions please contact me.

<< File: FDA-EPA Fish Advice briefing.pptx >> << File: Briefing agenda.doc >> << File: draft FR notice-fish advice.Version 1.docx >> << File: FISH_CHART_H_7.24.pdf >>

Subject:	Joint FDA/EPA Fish Advise call in **Ex. 6 - Personal Privacy** participant code Ex. 6 - Personal Privacy
Location:	3233 WJCE
Start:	Thu 7/30/2015 2:00 PM
End:	Thu 7/30/2015 2:45 PM
Recurrence:	(none)
Meeting Status:	Accepted
Organizer:	Kopocis, Ken
Required Attendees:	Southerland, Elizabeth; Hisel-Mccoy, Sara; Larimer, Lisa; Bigler, Jeff; Wathen, John
Optional Attendees:	Naidenko, Olga; Fontenelle, Albert; Conerly, Octavia

Poc Lisa Larimer 202-566-1017

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
From: Larimer, Lisa
Sent: Wed 7/29/2015 4:25:22 PM
Subject: RE: REVISED FILES for Ken briefing on FDA-EPA Fish Advisory

Crystal emailed me that she's leaving at 4. Any issues with getting materials over by then? If so, let me know and I'll take them over.

Thanks!

Lisa

From: Conerly, Octavia
Sent: Wednesday, July 29, 2015 12:24 PM
To: Larimer, Lisa
Subject: RE: REVISED FILES for Ken briefing on FDA-EPA Fish Advisory

Thanks Lisa.

Octavia Conerly

Special Assistant (on detail)

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Larimer, Lisa
Sent: Wednesday, July 29, 2015 12:19 PM
To: Conerly, Octavia
Subject: REVISED FILES for Ken briefing on FDA-EPA Fish Advisory

Here are versions of the Q&A and response to comments without comment bubbles (thanks again for catching that!) and an agenda where I subbed John Wathen for Sara Hisel-McCoy.

From: Conerly, Octavia
Sent: Wednesday, July 29, 2015 8:43 AM
To: Southerland, Elizabeth; Larimer, Lisa
Subject: RE: Ken briefing on FDA-EPA Fish Advisory looks great!

Great. I will send a copy and take 3 copies down to Ken's office today before 3pm.

Good job, Lisa.

Octavia Conerly

Special Assistant (on detail)

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Southerland, Elizabeth
Sent: Wednesday, July 29, 2015 8:32 AM
To: Conerly, Octavia; Larimer, Lisa
Subject: Ken briefing on FDA-EPA Fish Advisory looks great!

I have no comments because it is perfect!

To: Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Larimer, Lisa
Sent: Wed 7/29/2015 1:33:29 AM
Subject: Re: Discuss proposed edits to fish advice materials

Minor edits people have been proposing in both agencies as materials have gone up the review chains.

From: Bigler, Jeff
Sent: Tuesday, July 28, 2015 8:04 PM
To: Larimer, Lisa
Subject: Re: Discuss proposed edits to fish advice materials

What changes?

> On Jul 28, 2015, at 4:52 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:
>
> Call-in information:
> 1-855-564-1700 conference extension: **Ex. 6 - Personal Privacy**
>
> <meeting.ics>

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 7/28/2015 8:59:40 PM
Subject: Notes/questions re: fish advice for Betsy @ biweekly

- Meeting with OCHP is scheduled for today at 1:00
- Call with FDA to discuss edits proposed so far on Friday
- Any edits to agenda, presentation or other materials?
- Ask how best to share materials with Ken Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Barash, Shari[Barash.Shari@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 1/17/2017 9:46:10 PM
Subject: RE: Advice Call info for Betsy for 1/18

Sara just asked me to send to her for Evelyn to print out and run down to Betsy before she leaves.

From: Barash, Shari
Sent: Tuesday, January 17, 2017 4:38 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Wathen, John <Wathen.John@epa.gov>
Subject: Re: Advice Call info for Betsy for 1/18

Lisa,

I will send to Betsy and cc you both. I think I want to do it from a computer so she doesn't end up with the older attachment.

Shari

Sent from my iPhone

On Jan 17, 2017, at 3:45 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

> I found it a little disjointed, so I cleaned up the attachment a little. Also fixed some typos in the email:
>
> Betsy-
>
> The webpages go live at 8:45 AM on Wed. 1/18/17. The press release is posted at 9:15 AM.
>
> We have two calls for you to make at 9:15 AM:

1)

Ex. 5 - Deliberative Process

2)

Attachment shows which entities EPA is contacting (p. 1), suggested talking points (p. 2), and list of entities FDA is contacting (p. 3).

Shari, Sara, Lisa, and John

From: Wathen, John
Sent: Tuesday, January 17, 2017 3:07 PM
To: Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Advice Call info for Betsy for 1/18

Betsy-

The webpages go live at 8:45 AM 1/18/17. The press release is post 9:15 AM

They (FDA) have two calls for you to make:

Ex. 5 - Deliberative Process

And

Ex. 5 - Deliberative Process

Suggest talking points are included in the attached, as well as the list of entities FDA is calling.

Shari, Sara, Lisa, and John

John Wathen

Senior Science Advisor, Fish and Beach Programs

National Branch (4305 T)

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Standards and Health Protection Division

Office of Science and Technology

Office of Water

US Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, DC 20460

202-566-0367 phone

202-566-0409 fax

http://www.epa.gov/waterscience

<Fish advice rollout info & TPs 1-17-17.docx>

To: Abi-Khattar, Cathy[Cathy.Abi-Khattar@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
Cc: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; CFSAN-Webmaster[CFSAN-Webmaster@fda.hhs.gov]
From: Larimer, Lisa
Sent: Tue 1/17/2017 9:23:11 PM
Subject: RE: chart graphic on web page

Thank you! If anything does change, please loop in my webmaster at Kearney.renee@epa.gov

From: Abi-Khattar, Cathy [mailto:Cathy.Abi-Khattar@fda.hhs.gov]
Sent: Tuesday, January 17, 2017 4:14 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>
Subject: RE: chart graphic on web page

Here is the current version of everything. Below are the links that each piece will have when we are live tomorrow. Hope that helps.

Please note, if any of the attached change again this evening, I will resend the new versions to you.

Thanks

Cathy

QA English page
http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm534873.htm

QA English PDF
http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM537120.pdf

QA Spanish page
http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm537141.htm

QA Spanish PDF
http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM537166.pdf

FDA and EPA's Response to External Peer Review on the FDA-EPA's Technical Information on the Development
http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessm

External Peer Review Report: FDA-EPA's Technical Information on Development of Fish Consumption Advice (this is the report done by contractors)
http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessm

Cathy Abi-Khattar

CFSAN Web Team

5001 Campus Dr

College Park, MD 20740

240-402-1906

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, January 17, 2017 3:21 PM
To: Natanblut, Sharon; Abi-Khattar, Cathy
Cc: Smegal, Deborah
Subject: RE: chart graphic on web page

I suppose we can link to yours, but I'll need the direct link for each document.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, January 17, 2017 3:08 PM
To: Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: chart graphic on web page

That was my understanding but we need Lisa to confirm.

From: Abi-Khattar, Cathy
Sent: Tuesday, January 17, 2017 3:08 PM
To: Larimer, Lisa; Natanblut, Sharon
Cc: Smegal, Deborah
Subject: Re: chart graphic on web page

The images I sent is what I have.

For the other pieces, I was under the impression EPA is linking to our pieces. Sharon can you confirm? I can send the pieces if EPA is posting separate copies.

Thanks!

Cathy Abi-Khattar
CFSAN Web Branch

From: Larimer, Lisa

Sent: Tuesday, January 17, 2017 3:03 PM

To: Abi-Khattar, Cathy; Natanblut, Sharon

Cc: Smegal, Deborah

Subject: RE: chart graphic on web page

Thanks. I tried exporting a jpg of the full chart from the pdf, but it didn't come out clearly. Do you have a better version?

In addition, my webmaster is asking for (508-compliant) pdfs of the following, which I don't have:

- Q&A in English
- Q&A in Spanish
  - Summary of public comments and agency responses
  - Peer review report

I'm hoping you have them?

From: Abi-Khattar, Cathy [mailto:Cathy.Abi-Khattar@fda.hhs.gov]
Sent: Tuesday, January 17, 2017 12:37 PM
To: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: chart graphic on web page

Here is the image of the fish advice PDF and the image we are using for social media.

Our website development works differently so not sure how their side is going to code the same look and feel that we went with. Attached is a screenshot of how our page will look.

Thanks

Cathy

Cathy Abi-Khattar

CFSAN Web Team

5001 Campus Dr

College Park, MD 20740

240-402-1906

From: Natanblut, Sharon

Sent: Tuesday, January 17, 2017 12:35 PM
To: Abi-Khattar, Cathy; Larimer, Lisa
Subject: RE: chart graphic on web page

Do you want to send both? I'm not sure either! Also, do they have what's going on our landing page?

From: Abi-Khattar, Cathy
Sent: Tuesday, January 17, 2017 12:34 PM
To: Natanblut, Sharon; Larimer, Lisa
Subject: RE: chart graphic on web page

I am not sure what exactly we need to send. The social media image or just an image of the PDF?

Cathy Abi-Khattar

CFSAN Web Team

5001 Campus Dr

College Park, MD 20740

240-402-1906

From: Natanblut, Sharon
Sent: Tuesday, January 17, 2017 12:31 PM
To: Larimer, Lisa; Abi-Khattar, Cathy
Subject: RE: chart graphic on web page

Cathy, did you get back to Lisa on this? I'd love if we gave them everything we have if that's possible. Thanks.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]

Sent: Tuesday, January 17, 2017 10:15 AM
To: Natanblut, Sharon; Abi-Khattar, Cathy
Subject: chart graphic on web page

I think I mentioned that I really liked your idea of having the chart as a graphic on the web page. Since you've already converted it into graphic form, can I send that to my webmaster so she doesn't have to duplicate work that already been done?

Thanks!

Lisa

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Mon 10/26/2015 6:20:08 PM
Subject: FW: Senior Leadership Personnel Announcements

Let's hope the fish advice meeting doesn't get rescheduled again.

From: Message from the Administrator
Sent: Monday, October 26, 2015 12:40 PM
To: Message from the Administrator <messagefromtheadministrator@epa.gov>
Subject: Senior Leadership Personnel Announcements

Hi Everyone,

I have several personnel announcements regarding senior leadership, which will position EPA well and continue to steer us in the right direction for the remainder of this administration.

Ken Kopocis, our current Deputy Assistant Administrator for Water, will retire in early November, concluding 32 years of public service. Ken has been instrumental in leading the Office of Water, particularly in finalizing the historic Clean Water Rule that better protects our nation's water resources. Under his leadership, the Office of Water also finalized a rule to keep steam electric power plants from discharging 1.4 billion pounds of toxic pollutants into our waterways each year and a rule to protect billions of fish and other aquatic life from being drawn each year into cooling water systems at large power plants and factories. Additionally, he led efforts to dramatically expand the agency's assistance to

communities for green infrastructure, climate resilience, and urban waters. Prior to coming to EPA, for nearly 27 years Ken held leadership positions on both the Committee on Transportation and Infrastructure of the House of Representatives and the Committee on Environment and Public Works of the Senate where he worked primarily on water quality and water resources issues. I want to thank him for all his hard work and wish him the very best.

With Ken's retirement, I'm delighted that Joel Beauvais will assume the role of Acting Deputy Assistant Administrator for Water. Joel has been the Associate Administrator for Policy for the past two years, where he has served as one of my key policy advisors. Joel has played an important role in the development of high-profile rules across the Agency, has ably managed EPA's relationship with OMB on interagency review of regulations and has led EPA's efforts on economic analysis, climate adaptation, communities, and Lean. He is well versed in EPA's water policy priorities, and he brings to the table extensive experience with EPA policy across program offices and a broad and deep network within OMB, the White House and other federal agencies. Previously, Joel was Associate Assistant Administrator in the Office of Air and Radiation and Special Counsel to the Office of the Administrator in the Office of General Counsel. He previously served as Counsel to the House Committee on Energy and Commerce and clerked for Justice Sandra Day O'Connor on the U.S. Supreme Court. Joel's background makes him uniquely qualified to lead the Office Water in implementing the Clean Water Act and the Safe Drinking Water Act, and in achieving our priorities for the remainder of the Administration.

As Joel moves to Water, I'm pleased that Laura Vaught has agreed to become Acting Associate Administrator for the Office of Policy. As you know, Laura is currently the Associate Administrator for Congressional and Intergovernmental Relations (OCIR). She has advised me, other senior leadership and our colleagues at the White House on effectively engaging Congress, including at hearings and in requests for information. Laura has also been a tremendous asset in several major announcements, including the Clean Power Plan and the Clean Water Rule. Prior to coming to OCIR, Laura worked as Chief of Staff for Congressman Rick Boucher and as staff on the House Committee on Energy and Commerce. Her familiarity with EPA policy across all program offices, a broad and deep network within the White House and other federal agencies, and her negotiation skills make her the perfect choice to lead the Office of Policy.

Rounding out the leadership announcements brings us to Nichole Distefano. I'm happy that Nichole will assume the role of Acting Associate Administrator for OCIR. She has been in OCIR for over two years and currently serves as the Deputy Associate Administrator. Nichole has worked hand in hand with Laura in advising me and our senior leadership on our Congressional interactions. She has also played a pivotal role in the development and implementation of the rollout of our two flagship regulatory efforts, the Clean Power Plan and the Clean Water Rule, among other agency efforts. Prior to coming to EPA, she worked as senior legislative counsel for Senator Claire McCaskill. Her strong legislative expertise in energy, environment, agriculture policy, federal contracting policy and domestic security matters makes her exceptionally qualified to lead OCIR.

Please join me in thanking Ken for his service and congratulating Joel, Laura, and Nichole on their new roles.

Gina

To: Lalley, Cara[Lalley.Cara@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]
Cc: Christensen, Christina[Christensen.Christina@epa.gov]; McDonald, Ambria[McDonald.Ambria@epa.gov]
From: Larimer, Lisa
Sent: Tue 9/15/2015 3:27:08 PM
Subject: RE: PLEASE PROVIDE INPUT: draft rollout plan for 2015 FDA-EPA Fish Consumption Advice

OK, so we will ignore those (unless John has already started editing them).

From: Lalley, Cara
Sent: Tuesday, September 15, 2015 11:26 AM
To: Larimer, Lisa; Wathen, John; Fontenelle, Samantha
Cc: Christensen, Christina; McDonald, Ambria
Subject: RE: PLEASE PROVIDE INPUT: draft rollout plan for 2015 FDA-EPA Fish Consumption Advice

Yes- I will have Travis ask the FDA comms folks to make sure those answers are updated (or deleted or modified to reflect the final fish advice)—you can also feel free to share them with the technical folks you've been working with in the interim. Thanks

From: Larimer, Lisa
Sent: Tuesday, September 15, 2015 11:20 AM
To: Lalley, Cara; Wathen, John; Fontenelle, Samantha
Cc: Christensen, Christina; McDonald, Ambria
Subject: RE: PLEASE PROVIDE INPUT: draft rollout plan for 2015 FDA-EPA Fish Consumption Advice

Cara, I need some clarification. The Q&A have [FDA] or [EPA] or a combination next to them. Does that mean you've already worked out with FDA that they will update the ones with [FDA]?

From: Lalley, Cara
Sent: Monday, September 14, 2015 5:44 PM
To: Wathen, John; Fontenelle, Samantha; Larimer, Lisa
Cc: Christensen, Christina; McDonald, Ambria

Subject: PLEASE PROVIDE INPUT: draft rollout plan for 2015 FDA-EPA Fish Consumption Advice
Importance: High

Please review this draft rollout plan. In particular, please add in the "anticipated reactions" of your various stakeholder groups by COB this Wed. Please respond to the other comments/questions and update the "EPA" Q&A by COB this Friday.

Travis will review and share this draft with relevant comm folks here in EPA and the team he's begun working with at FDA.

We'd like to have a joint rollout plan for the final advice instead of just a joint set of key messages and Q&A as we did in 2014. There will be many details to keep track of in planning for October between the two agencies.

Thanks,

Cara Lalley

Communications Coordinator

Office of Science & Technology

U.S. EPA Office of Water

(202)566-0372 (p)

(202)566-1140 (f)

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
Cc: Jones, William[William.Jones@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Strachman-Miller, Jason[Jason.Strachman-Miller@fda.hhs.gov]
From: Larimer, Lisa
Sent: Tue 7/28/2015 7:54:04 PM
Subject: RE: seafood advice briefing

Somehow I am free on Friday except from about 11:30-2:00. I nominate the person with the craziest schedule to pick a time. We can use one of my conference numbers if you like.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, July 28, 2015 2:59 PM
To: Larimer, Lisa
Cc: Jones, William; Smegal, Deborah; Strachman-Miller, Jason
Subject: RE: seafood advice briefing

Works for me too.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, July 28, 2015 2:58 PM
To: Natanblut, Sharon
Cc: Jones, William; Smegal, Deborah; Strachman-Miller, Jason
Subject: RE: seafood advice briefing

We've been receiving minor comments, too. So far we don't have many, so it would probably be most expeditious if you sent yours in track changes, then we'll add ours. Then let's talk at the end of the week. I know Debbie is out this week; does Friday work for the rest of you ?

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, July 28, 2015 12:20 PM
To: Larimer, Lisa
Cc: Jones, William; Smegal, Deborah; Strachman-Miller, Jason
Subject: FW: seafood advice briefing

Hi Lisa,

Here are the materials that we put into clearance, as well as the PPT we used last week to brief our Center director and Deputy Commissioner. We will use them again tomorrow to brief our Commissioner.

Bill may have mentioned to you that we are receiving comments from our attorneys, particularly on additional info we need to provide in the draft FR notice and some relatively minor, I think, comments on the Q&A and response to comments. We may be able to get those reviewed by Bill and Deb and the attorneys to be okay by the end of this week and then we can share those edits (in track changes) with you. Or we could work it differently if you have any suggestions. Bill is in a better position than I am to discuss their suggestions.

It may be good to have a conference call later this week to walk through everything. What do all of you think?

Thanks.

Sharon

From: Natanblut, Sharon
Sent: Tuesday, July 28, 2015 11:09 AM
To: Novak, Benjamin
Subject: seafood advice briefing

7/21 update – materials attached.

- Briefing PPT

- Fish advice – horizontal, vertical, and original proposed

- Draft FR notice

- Response to comments

- Supplemental QAs

- technical appendix (i.e., sortable table of fish species, how the chart was derived, and recommended portion sizes for children based on age)

To: Berger, Martha[Berger.Martha@epa.gov]
From: Larimer, Lisa
Sent: Tue 7/28/2015 7:47:54 PM
Subject: RE: Requesting an informal meeting on FDA-EPA updated fish advice

C or D? I'll try to add it to a meeting invite, but I might not have permission.

From: Berger, Martha
Sent: Tuesday, July 28, 2015 3:39 PM
To: Larimer, Lisa; Firestone, Michael
Cc: Wathen, John; Reed, Khesha
Subject: RE: Requesting an informal meeting on FDA-EPA updated fish advice

It looks as if our conference room, in 1144 west, will be free.

Martha Berger

Office of Children's Health Protection

US Environmental Protection Agency

202/564-2191

From: Larimer, Lisa
Sent: Tuesday, July 28, 2015 2:27 PM
To: Firestone, Michael
Cc: Berger, Martha; Wathen, John; Reed, Khesha
Subject: RE: Requesting an informal meeting on FDA-EPA updated fish advice

Let's plan on 1:00 then. We're more than happy to come see you, if you'd like to reserve a room. Otherwise it looks as if one of our conference rooms is open then. Happily we're both in West, so it's not a long trip either way. Your choice.

From: Firestone, Michael

Sent: Tuesday, July 28, 2015 2:22 PM
To: Larimer, Lisa
Cc: Berger, Martha; Wathen, John; Reed, Khesha
Subject: Re: Requesting an informal meeting on FDA-EPA updated fish advice

Lisa

Either time is fine.

Michael P. Firestone, Ph.D.

Regulatory Support & Science Policy Division

Office of Children's Health Protection (MC 1107T)

Office of the Administrator

U.S. Environmental Protection Agency

Room 1130 EPA West Building

Washington, DC 20460

Office: 202-564-2199 (Monday thru Wednesday)

Cell: 202-213-4651 (Thursday)

FAX: 202-564-2733

On Jul 28, 2015, at 2:18 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

> Thank you, Martha.
>
> Michael – are you available at 11 or 1 tomorrow?
>
> **Lisa Larimer, P.E.** | Team Leader
>
> U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Berger, Martha
Sent: Tuesday, July 28, 2015 2:00 PM
To: Larimer, Lisa; Firestone, Michael
Cc: Wathen, John; Reed, Khesha
Subject: RE: Requesting an informal meeting on FDA-EPA updated fish advice

Lisa, Michael Firestone can meet with you tomorrow – can y'all work out the best time?

Martha Berger

Office of Children's Health Protection

US Environmental Protection Agency

202/564-2191

From: Berger, Martha
Sent: Tuesday, July 28, 2015 11:09 AM
To: Larimer, Lisa
Cc: Wathen, John; Michael Firestone; Khesha Reed
Subject: RE: Requesting an informal meeting on FDA-EPA updated fish advice

Thanks, Lisa. We are trying to pull together a time to meet with you before Thursday.

Martha

Martha Berger

Office of Children's Health Protection

US Environmental Protection Agency

202/564-2191

From: Larimer, Lisa
Sent: Tuesday, July 28, 2015 10:58 AM
To: Berger, Martha
Cc: Wathen, John
Subject: Requesting an informal meeting on FDA-EPA updated fish advice

Martha,

We in the Office of Science and Technology would love to update you on what the final version of the FDA-EPA fish advice is looking like and how CHPAC's recommendations were addressed. In an ideal world, we'd like to meet with Ruth Etzel and whichever staff are interested in this project before we brief our AA on Thursday afternoon. Whatever magic you can work on your end would be much appreciated.

Here are some relevant files in case people want to take a look before the meeting.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Martinez, Menchu[martinez.menchu-c@epa.gov]
From: Larimer, Lisa
Sent: Mon 9/14/2015 4:25:11 PM
Subject: For today's staff meeting

Fish

•□□□□□□ We are briefing Stan Meiburg on the fish advice next Tuesday. Will share shortened briefing with Sara by the time she gets in on Wed, if not today.

•□□□□□□ The kick-off meeting for the OIG review of fish advisories will probably be next Tuesday also.

•□□□□□□ Need sign-off on Leanne's abstract for a poster presentation to submit to the National Water Quality Monitoring Conference. Deadline is this Friday.

•□□□□□□ Date for contractor submittals on peer review of fish consumption survey guidance has been extended to this Friday (9/18). This was due to a delay in the contracts person answering submitted questions about the task order – her system was down.

Beach

•□□□□□□ We have a check-in with the OIG on the beach program review on Tuesday

•□□□□□□ Tracy is working on the 1st FR notice for the beach grant ICR renewal – our goal is to get something to Sara to review/sign off on late this week

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Larimer, Lisa
Sent: Wed 6/3/2015 4:12:57 PM
Subject: RE: Here's the draft FR notice for the fish advice

Nope, we're just helping them out with the text.

From: Bigler, Jeff
Sent: Wednesday, June 03, 2015 12:12 PM
To: Larimer, Lisa
Subject: Re: Here's the draft FR notice for the fish advice

BTW - FDA developed and (thankfully) issued the last 2 FRNs. Hopefully they don't think EPA is volunteering (?) to issue this next FRN since we're apparently taking the lead on developing the text? FDA seemed to do a fine job with the past FRNs.

Just a thought.

On Jun 3, 2015, at 11:51 AM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

> I'd like to send it to FDA before next week's meeting, possibly on Friday so they have a few days to read it. If you get a chance to read it by noon on Friday and have suggestions, let me know. Thanks!

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

<draft FR notice-fish advice.docx>

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
From: Larimer, Lisa
Sent: Tue 7/28/2015 7:08:22 PM
Subject: Materials for Ken briefing on FDA-EPA fish advice
Briefing agenda.doc
FDA-EPA Fish Advice briefing.pptx
draft FR notice-fish advice.Version 1.docx
FISH_CHART_H_7.24.pdf
FISH_CHART_V_7.24.pdf
Responses to comments-072315.docx
technical web page-fish advice-072315.docx
Fish Advice Qs and As-070915.docx

Octavia-

Here are the materials for Betsy's review:

- Agenda
- Presentation
- 2 charts
- Q&A
- Response to comments
- *Federal Register* notice
- Text for technical web page (I wasn't planning to sending this to Ken in advance unless she thinks we should)

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Naidenko, Olga[Naidenko.Olga@epa.gov]
From: Larimer, Lisa
Sent: Wed 6/3/2015 4:10:04 PM
Subject: RE: Here's the draft FR notice for the fish advice

Thank you! That was fast!

From: Naidenko, Olga
Sent: Wednesday, June 03, 2015 12:06 PM
To: Larimer, Lisa; Wathen, John; Fontenelle, Samantha; Bigler, Jeff
Subject: RE: Here's the draft FR notice for the fish advice

It reads very good to me.

Two thoughts on paragraph in third column, first page

Ex. 5 - Deliberative Process

And on this sentence Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

How about adding Ex. 5 - Deliberative Process for clarity?

"Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process"

I do understand that this sentence Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process But the sentence as it stands right now seems a little bit confusing, even though the overall paragraph explains the specific meaning.

Hope this is useful,

Olga

From: Larimer, Lisa
Sent: Wednesday, June 03, 2015 11:52 AM
To: Wathen, John; Fontenelle, Samantha; Bigler, Jeff; Naidenko, Olga
Subject: Here's the draft FR notice for the fish advice

I'd like to send it to FDA before next week's meeting, possibly on Friday so they have a few days to read it. If you get a chance to read it by noon on Friday and have suggestions, let me know. Thanks!

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Moore, Keara[Moore.Keara@epa.gov]
From: Larimer, Lisa
Sent: Tue 1/17/2017 7:09:16 PM
Subject: RE: Ex. 5 - Deliberative Process version of fish advice materials

Thank you!

From: Moore, Keara
Sent: Tuesday, January 17, 2017 1:06 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: FW: Ex. 5 - Deliberative Process version of fish advice materials

See attached for some additional edits from Trang on the Ex. 5 - Deliberative Process documents.

Keara Moore

Acting Associate Chief

National Branch, SHPD

Office of Science and Technology

Office of Water

U.S. Environmental Protection Agency

Washington, DC

Ph: 202-564-3173

From: Le, Trang
Sent: Tuesday, January 17, 2017 8:21 AM
To: Moore, Keara <Moore.Keara@epa.gov>
Subject: Fw: Ex. 5 - Deliberative Process version of fish advice materials

Keara -- Sorry could you please use this latest version? Please disregard the one

yesterday. Thanks!

From: Le, Trang
Sent: Monday, January 16, 2017 11:23 PM
To: Moore, Keara
Subject: Re: Ex. 5 - Deliberative Process version of fish advice materials

Your're welcome. Glad to know it's helpful.

Not sure if it's too late for you or not, but during this long weekend, I've just finished the edits for your other translation document (attachment). So forward it to you just in case for the complete document set . See you next month.

Thanks,

Trang Le

U.S. Environmental Protection Agency

Office of Ground Water and Drinking Water

Drinking Water Protection Division

Phone: (202) 564-1572

Email: le.trang@epa.gov

From: Moore, Keara
Sent: Friday, January 13, 2017 8:49:41 AM
To: Le, Trang
Cc: Plastino, Michael

Subject: RE: Ex. 5 - Deliberative Process version of fish advice materials

Thank you so much!!! This is exactly what I needed. Sorry to put extra work on you! I really appreciate it.

Copying Michael to make sure he is aware of the extra work you've done. I'll be back on Feb 6 and looking forward to seeing everyone. ☺

Keara Moore

Acting Associate Chief

National Branch, SHPD

Office of Science and Technology

Office of Water

U.S. Environmental Protection Agency

Washington, DC

Ph: 202-564-3173

From: Le, Trang
Sent: Thursday, January 12, 2017 9:40 PM
To: Moore, Keara <Moore.Keara@epa.gov>
Subject: Re: Ex. 5 - Deliberative Process version of fish advice materials

Keara,

Please see my response below (highlight). Sorry my new project is rolling out, so I couldn't send you my response earlier. Basically the Ex. 5 - Deliberative Process translation is not too bad -- just not quite an easy read because normal people usually don't write/speak that way. I tried to help out with my edits on one translation document, and hopefully it could make the reading smoother. If you have additional time, I could help you out to complete the edit for your other document.

Hope it helps.

Thanks,

Trang Le

U.S. Environmental Protection Agency

Office of Ground Water and Drinking Water

Drinking Water Protection Division

Phone: (202) 564-1572

Email: le.trang@epa.gov

From: Moore, Keara
Sent: Friday, January 6, 2017 10:28:40 AM
To: Le, Trang
Cc: Plastino, Michael
Subject: FW: Ex. 5 - Deliberative Process version of fish advice materials

Hello, Trang!

I hope all is well with you! I have a totally random favor to ask of you. Feel free to say no if it would be a problem. I'm copying Michael so that he is aware of my request.

My office has some documents we are trying to get out in multiple languages. We found

out that one of the translations is bad and so are looking for people to give the others a quick read so we can see how extensive the problem might be. I believe you speak Ex. 5 - Deliberative Process so you came to mind as somebody who might be able to help us out.

We would need input by the 12th. There are about 8 pages and we don't need a thorough review of the grammar or anything like that, just the general quality of the translation. Our question is, when you read this, does it make sense and sound normal?

Yes and No. The Ex. 5 - Deliberative Process translation is not too bad, but it's not smoothly reading either. In some places, it's hard to understand because of two language structures are different. In this case, the Ex. 5 - Deliberative Process translation was used the same English language structure. So that causes some issues to understand the meaning the article tries to convey to its audience.

Does it sound like it comes from a professional agency who knows what it's talking about, or does it sound like we just stuck it in Google translator?

Yes, the article meaning sounds knowledgeable thru extensive research. Absolutely it's not like raw outcomes from Google translator.

If the translation is bad, when we release the English version we can just hold this one back so we have time to fix it, but ideally, we would get them all out at the same time.

Again, if it would be a problem to take it on, please feel free to say no! If you do have time, the documents are attached in both the Ex. 5 - Deliberative Process and English versions. Give me a call if you need any more information.

Thank you!

Keara Moore

Acting Associate Chief

National Branch, SHPD

Office of Science and Technology

Office of Water

U.S. Environmental Protection Agency

Washington, DC

Ph: 202-564-3173

From: Larimer, Lisa
Sent: Thursday, January 05, 2017 7:29 PM
To: Moore, Keara <Moore.Keara@epa.gov>
Subject: FW: Ex. 5 - Deliberative Process version of fish advice materials

I hit send too quickly. Here are the English versions too.

From: Larimer, Lisa
Sent: Thursday, January 05, 2017 7:27 PM
To: Moore, Keara <Moore.Keara@epa.gov>
Subject: Ex. 5 - Deliberative Process version of fish advice materials

Hi Keara,

Here are the Ex. 5 - Deliberative Process translations I received for the fish advice. I'm also attaching the English versions they worked from. If your colleague could look at it by Jan. 12 and let me know if there are issues, that would be great. Bonus points if she can fix any problems!

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
From: Larimer, Lisa
Sent: Fri 9/11/2015 6:05:16 PM
Subject: RE: FDA-EPA Fish Advice

Never mind. I got word from higher up to keep it on Tuesday. Thanks!

From: Conerly, Octavia
Sent: Friday, September 11, 2015 1:17 PM
To: Larimer, Lisa
Subject: RE: FDA-EPA Fish Advice

Lisa,
I don't know.

Octavia Conerly
Special Assistant to the Office Director
Office of Science and Technology
1200 Pennsylvania Ave. NW MC 4304T
Room 5231H
Washington, DC 20460
EMAIL: conerly.octavia@epa.gov
PHONE: (202) 566-1094
FAX: (202) 566-0441

From: Larimer, Lisa
Sent: Friday, September 11, 2015 11:14 AM
To: Conerly, Octavia
Subject: RE: FDA-EPA Fish Advice

Just now saw this. Looking into it. Any particular time on Friday?

From: Conerly, Octavia
Sent: Friday, September 11, 2015 10:20 AM
To: Larimer, Lisa
Subject: FW: FDA-EPA Fish Advice

Would you be agreeable to next Friday, the 18th? If not it's the 22nd (you already have a reschedule for this date). Let me know ASAP.

Octavia Conerly
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Office of Science and Technology

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Washington, DC 20460
EMAIL: conerly.octavia@epa.gov
PHONE: (202) 566-1094
FAX: (202) 566-0441

From: Klasen, Matthew
Sent: Friday, September 11, 2015 9:33 AM
To: Conerly, Octavia; Bethel, Heidi
Cc: Penman, Crystal
Subject: RE: FDA-EPA Fish Advice

I've passed this along to Denise Anderson (Stan's scheduler) and hopefully she can find another time - which is a bit more challenging next week given Ken's Iowa trip.

Octavia, do you know if staff folks would be able to make next Friday work if needed? That could end up being the only viable alternative next week.

Thanks,
Matt

From: Conerly, Octavia
Sent: Friday, September 11, 2015 9:02 AM
To: Bethel, Heidi; Klasen, Matthew
Cc: Penman, Crystal
Subject: RE: FDA-EPA Fish Advice

Thank you!

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EMAIL: conerly.octavia@epa.gov
PHONE: (202) 566-1094
FAX: (202) 566-0441

From: Bethel, Heidi
Sent: Friday, September 11, 2015 8:59 AM

To: Conerly, Octavia; Klasen, Matthew
Cc: Penman, Crystal
Subject: RE: FDA-EPA Fish Advice

Adding Crystal as an FYI.

From: Conerly, Octavia
Sent: Friday, September 11, 2015 8:58 AM
To: Klasen, Matthew
Cc: Bethel, Heidi
Subject: FDA-EPA Fish Advice

Good morning Matt,
Is it possible to get this meeting moved up (time-wise)? Many of the principle participants have to leave before 5pm to pick up their kids. I was asked to beg for an earlier time. So here goes....PLEASE! PLEASE! PLEASE!

Subject:	FDA-EPA Fish Advice
Location:	DCRoomARN3530CFTB/DC-Ariel-Rios-AO
Start:	Thu 9/17/2015 5:00 PM
End:	Thu 9/17/2015 5:45 PM
Recurrence:	(none)
Meeting Status:	Accepted
Organizer:	Meiburg, Stan
Required Attendees:	Larimer, Lisa; Wathen, John; Hisel-Mccoy, Sara; Southerland, Elizabeth; Kopocis, Ken; Gilinsky, Ellen; Burke, Thomas; Etzel, Ruth; Coopwood, Theodore; Mitchell, Stacey; Schroer, Lee; Klasen, Matthew; Ingram, Amir
Optional Attendees:	Loop, Travis; Lalley, Cara; Kavlock, Robert; Hauchman, Fred; Schoeny, Rita; Reed, Khesha; Firestone, Michael; Penman, Crystal; Gentry, Nathan

Point of Contact for the Meeting: Lisa Larimer 566-1017
SCt: Denise Anderson, 564-1782

Purpose: Share the final joint FDA-EPA fish advice with EPA senior leadership. HHS senior leadership is receiving a comparable briefing. The workgroup's goal is to announce the advice in September/October 2015, contingent upon timing of review by HHS and OMB.

Background:	An FDA-EPA workgroup has developed an update to the March 2004 fish advisory on mercury in fish and shellfish. The advice recommends consumption frequencies for the target audience of pregnant and breastfeeding women, women who could become pregnant, and children.
Last possible date for the meeting:	After 9/9/15 and before 9/25/15
EPA Staff (Required):	OW: Lisa Larimer, John Wathen, Sara Hisel-McCoy, Elizabeth Southerland, Ken Kopocis, Ellen Gilinsky ORD: Thomas Burke OA: Ruth Etzel, Theodore Coopwood OGC: Stacey Mitchell, Lee Schroer
EPA Staff (Optional):	OW: Travis Loop, Cara Lalley ORD: Robert Kavlock, Fred Hauchman, Rita Schoeny OA: Khesha Reed, Michael Firestone

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
From: Larimer, Lisa
Sent: Fri 9/11/2015 3:13:40 PM
Subject: RE: FDA-EPA Fish Advice

Just now saw this. Looking into it. Any particular time on Friday?

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EMAIL: conerly.octavia@epa.gov
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Optional Attendees:	Loop, Travis; Lalley, Cara; Kavlock, Robert; Hauchman, Fred; Schoeny, Rita; Reed, Khesha; Firestone, Michael; Penman, Crystal; Gentry, Nathan

Point of Contact for the Meeting: Lisa Larimer 566-1017
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EPA Staff (Optional):	OW: Travis Loop, Cara Lalley ORD: Robert Kavlock, Fred Hauchman, Rita Schoeny OA: Khesha Reed, Michael Firestone

To: Hisel-Mccoy, Sara[Hisel-McCoy.Sara@epa.gov]
Cc: Shari Barash[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Fri 6/26/2015 4:26:12 AM
Subject: Another super successful meeting with FDA on the fish advice
Meeting Summary-062515 FDA-EPA fish advice.docx

Sara-

We had a great meeting with FDA today. We made final edits to all the materials (chart, Qs & As, responses to comments, FR notice). Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process we'll be ready for management review. The group is developing communication materials and has come up with a schedule for management review. FDA is pushing to get it out quickly.

- Week of July 13: Send entire package to EPA OST Director Betsy Southerland, FDA CFSAN Director Dr. Susan Mayne, and FDA Deputy Commissioner Mike Taylor.

- Week of July 20: Brief the people listed above.

- Week of July 27: EPA Deputy Assistant Administrator Ken Kopocis and FDA Acting Commissioner Dr. Stephen Ostroff

- August: EPA Administrator Gina McCarthy and HHS Secretary Sylvia Burwell, then OMB

Could you ask Betsy:

1. if she'd like a briefing

2. whether she wants to talk to Ken about the advice or have us give him a briefing

3. if she'd ask Ken if the Administrator needs a briefing

We'll need to start the scheduling process ASAP if everyone wants to briefed. Thanks!

I'm including the meeting summary if you'd like more detailed information.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: David.Shapinsky@fda.hhs.gov[David.Shapinsky@fda.hhs.gov]
Cc: Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]; Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 9/9/2015 7:31:48 PM
Subject: Translations of FDA-EPA fish advice

Hi David,

I know Sharon Natanblut is out until Sept. 24, so I am hoping you can help me. Our communications people are asking if we are planning to have the fish advice translated into other languages before release. I doubt our public affairs office will let us release it only in English. We ***might*** be able to if we have a definite plan for when translations will be available.

Is this something Sharon has discussed with any of you?

According to one of my staff, we translated the 2004 advice in the following languages:

- □□□□□□□ Spanish
- □□□□□□□ Cambodian
- □□□□□□□ Chinese
- □□□□□□□ Hmong
- □□□□□□□ Korean
- □□□□□□□ Portuguese
- □□□□□□□ Vietnamese

The English and Spanish are the most requested. We may want to consider Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E.

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Jones, William[William.Jones@fda.hhs.gov]
From: Larimer, Lisa
Sent: Fri 5/22/2015 7:22:41 PM
Subject: RE: Larimer, Lisa wants to share FDA-EPA fish advice

Yay! Glad to hear when technology works as it is supposed to. Have a great holiday weekend and two weeks off!

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Friday, May 22, 2015 3:21 PM
To: Larimer, Lisa
Subject: RE: Larimer, Lisa wants to share FDA-EPA fish advice

Got it – thanks! This time it opened right up.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Friday, May 22, 2015 3:20 PM
To: Jones, William
Subject: RE: Larimer, Lisa wants to share FDA-EPA fish advice

I resent. Let me know if you did not get it.

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Friday, May 22, 2015 2:02 PM
To: Larimer, Lisa
Cc: Smegal, Deborah
Subject: FW: Larimer, Lisa wants to share FDA-EPA fish advice

I couldn't get back in to the folder. If you get a chance, could you resend the invitation?

Thanks,

Bill

That didn't work

We're sorry, but this invitation has expired. Please ask for a new invitation to this site.

If that doesn't help, contact the person who invited you and include these technical details:

Correlation ID: 3aef089d-4029-2000-07c3-e06f8cb8cc92

Date and Time: 5/22/2015 10:58:37 AM

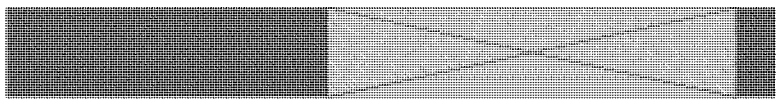
URL: **Ex. 5 - Deliberative Process**

User: william.jones@fda.hhs.gov

Issue Type: Invitation Expired.

From: Microsoft Online Services Team [mailto:msonlineservicesteam@email.microsoftonline.com]
Sent: Thursday, May 14, 2015 1:01 PM
To: Jones, William
Subject: Larimer, Lisa wants to share FDA-EPA fish advice

View this email in your browser



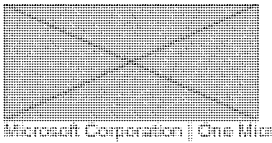
Hello,
Here's the link to the folder with fish advice files. For those of you in FDA, you may need to set up a Microsoft account if you don't already have one. I'm told it is very easy to do. If there is someone else who needs access, please let me

Open FDA-EPA fish

know.

advice

This is a mandatory service communication. To set your contact preferences for other communications, click here.



Microsoft Corporation | One Microsoft Way Redmond, WA 98052-6399

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Wed 9/9/2015 4:26:44 PM
Subject: RE: latest versions of fish advice documents

I will. Is there a new horizontal version of the chart?

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Tuesday, September 08, 2015 10:51 AM
To: Jones, William; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Subject: latest versions of fish advice documents

Hi,

Here are the latest versions, that include the updated fish chart from last week. Lisa can you please make sure these get into the EPA/FDA sharepoint directory?

Thanks

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Klasen, Matthew[Klasen.Matthew@epa.gov]; Bethel, Heidi[Bethel.Heidi@epa.gov]
Cc: Penman, Crystal[Penman.Crystal@epa.gov]; Conerly, Octavia[Conerly.Octavia@epa.gov]
From: Larimer, Lisa
Sent: Wed 9/9/2015 4:13:33 PM
Subject: RE: Checking on status of Administrator meeting request on EPA-FDA fish advice

Thanks, Matt!

From: Klasen, Matthew
Sent: Wednesday, September 09, 2015 12:10 PM
To: Bethel, Heidi
Cc: Larimer, Lisa; Penman, Crystal; Conerly, Octavia
Subject: RE: Checking on status of Administrator meeting request on EPA-FDA fish advice

That's a good and very timely question.

This morning I learned that this wasn't immediately scheduled because folks think that doing a briefing first for Stan would make sense, followed (if needed) by a shorter briefing for the Administrator. So you can expect a meeting invite to show up shortly from Stan.

I'll keep tabs on this and will check in with Stan's scheduling folks first thing tomorrow if I haven't heard anything by then. I'm hopeful they can find a time to do this next week.

Thanks,
Matt

From: Bethel, Heidi
Sent: Wednesday, September 09, 2015 10:53 AM
To: Klasen, Matthew
Cc: Larimer, Lisa; Penman, Crystal; Conerly, Octavia
Subject: RE: Checking on status of Administrator meeting request on EPA-FDA fish advice

Matt,

Do you know the status of this meeting request?

Thanks,

Heidi

From: Larimer, Lisa
Sent: Wednesday, September 09, 2015 10:51 AM
To: Bethel, Heidi; Penman, Crystal
Subject: Checking on status of Administrator meeting request on EPA-FDA fish advice

Hi! I'm back from vacation and checking on the status of scheduling this meeting. It looks like Crystal sent to scheduling on 8/28, but I haven't seen a meeting invitation.

Thanks!

Lisa

From: Penman, Crystal
Sent: Friday, August 28, 2015 12:38 PM
To: Bethel, Heidi
Cc: Ruf, Christine; Klasen, Matthew; Larimer, Lisa; Conerly, Octavia
Subject: RE: Meeting request materials for fish advice

Sent to scheduling.

From: Bethel, Heidi
Sent: Thursday, August 27, 2015 6:24 PM
To: Penman, Crystal
Cc: Ruf, Christine; Klasen, Matthew; Larimer, Lisa; Conerly, Octavia
Subject: Fwd: Meeting request materials for fish advice

Forwarding to Crystal for processing on Friday. Does Ken need an update on the USDA/ HHS meeting before Admin meeting? I am on annual leave so I have not reviewed these materials.

Just keeping it moving.

Heidi

Sent from my iPhone

Begin forwarded message:

From: "Larimer, Lisa" <Larimer.Lisa@epa.gov>
Date: August 27, 2015 at 5:35:05 PM EDT
To: "Bethel, Heidi" <Bethel.Heidi@epa.gov>, "Conerly, Octavia" <Conerly.Octavia@epa.gov>, "Klasen, Matthew" <Klasen.Matthew@epa.gov>
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We finally met with HHS and USDA on the confluence of our fish advice with their Dietary Guidelines for Americans and we are good to go. Here are the meeting request and memo for the briefing for the Administrator.

FYI, I won't be in the office tomorrow through Labor Day. John will be in the office tomorrow morning, but then out until Sept. 10. Hopefully you won't have any questions. If you do and can't reach us, try Samantha Fontenelle.

Thanks!

Lisa

To: Hisel-Mccoy, Sara[Hisel-McCoy.Sara@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]; Shari Barash[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Wed 9/9/2015 4:13:18 PM
Subject: BREAKING UPDATE: status of Administrator meeting request on EPA-FDA fish advice

Looks like we'll be briefing Stan first, possibly next week.

From: Klasen, Matthew
Sent: Wednesday, September 09, 2015 12:10 PM
To: Bethel, Heidi
Cc: Larimer, Lisa; Penman, Crystal; Conerly, Octavia
Subject: RE: Checking on status of Administrator meeting request on EPA-FDA fish advice

That's a good and very timely question.

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Lisa

To: Hisel-Mccoy, Sara[Hisel-McCoy.Sara@epa.gov]
Cc: Shari Barash[Barash.Shari@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Wed 9/9/2015 3:14:13 PM
Subject: Status of EPA-FDA fish advice

Sara –

Ex. 5 - Deliberative Process

•□□□□□□ **Status of meeting with Administrator:** OW (Crystal P) sent the request on Aug. 28. Matt and Heidi are checking on it.

•□□□□□□ **Status of HHS clearance:** The FDA folks have a briefing with the HHS Secretary on Friday, Sept. 18 at 2:00.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Bigler, Jeff[Bigler.Jeff@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 5/19/2015 1:48:41 PM
Subject: RE: Follow-up from May 15 FDA-EPA fish advice meeting

Thanks!

From: Bigler, Jeff
Sent: Monday, May 18, 2015 10:04 AM
To: Larimer, Lisa
Cc: Wathen, John
Subject: RE: Follow-up from May 15 FDA-EPA fish advice meeting

Here are the comments that were included from Healthy Mothers, Healthy Babies (#214) related to the fetus. There are other comments from them regarding language (e.g., servings instead of ounces)

Synthesized Comments table:

Page 4, "Provide more information on the benefits of eating fish while pregnant, such as the development it supports in the fetus, and more specifically what the dangers are in not getting enough of the fatty acids (D202, D0214, D0221, D0213, D0219, D0138, D0227, 0097, 0095,)" and "Stress that there is evidence showing moderate levels of fish consumption has a significant and positive effect on a fetus/child's IQ (D0206, D0214, D0219)"

Page 7, "Stress that there is evidence showing moderate levels of fish consumption has a significant and positive effect on a fetus/child's IQ (D0206, D0214, D0219)"

In the All Public Comments doc:

Page 18, "The new advice retains the recommendation that expecting moms should "limit white

(albacore) tuna to 6 ounces a week." However, according to data in your net effects report which evaluates the benefits of seafood at the species level [A Quantitative Assessment of the Net Effects on Fetal Neurodevelopment From Eating Commercial Fish (As Measured by IQ and also by Early Age Verbal Development in Children, available at: http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm393211.htm], pregnant women can safely consume up to 67 ounces of canned albacore tuna per week - that's 33 servings per week and more than 11 times the limit you are proposing to recommend. This recommendation is not scientifically justified. (FDA-2014-N-0595-0047/FDA-2014-N-0595-0049, similar comments in FDA-2014-N-0595-0097, FDA-2014-N-0595-DRAFT-0206, FDA-2014-N-0595-DRAFT-0214, FDA-2014-N-0595-DRAFT-0217, FDA-2014-N-0595-DRAFT-0218, FDA-2014-N-0595-DRAFT-0221, FDA-2014-N-0595-DRAFT-0227, FDA-2014-N-0595-DRAFT-0232) "

Page 25, "The advisory might be more effective if there is more information on the benefits of eating fish while pregnant, such as the development it supports in the fetus, and more specifically what the dangers are in not getting enough of the fatty acids (FDA-2014-N-0595-DRAFT-0110). Benefits to highlight include cardiovascular health for mothers and neurodevelopmental and eye benefits to children (FDA-2014-N-0595-DRAFT-0202, FDA-2014-N-0595-DRAFT-0214, FDA-2014-N-0595-DRAFT-0221). It is important to explain to women why seafood intake in the childbearing years is the best advice we can give for their current and future health, and the development of their infants. This advice will empower women to choose seafood intake on a regular basis. (FDA-2014-N-0595-DRAFT-0213, FDA-2014-N-0595-DRAFT-0219)"

Page 42, "The message to the public should stress that there is evidence showing moderate levels of fish consumption has a significant and positive effect on a fetus/child's IQ. More women would heed this advice and attain benefits for themselves and their children if the overall message was more positive and encouraging- shift to positive framing. (FDA-2014-N-0595-DRAFT-0206, FDA-2014-N-0595-DRAFT-0214, FDA-2014-N-0595-DRAFT-0219)"

From: Larimer, Lisa
Sent: Thursday, May 14, 2015 1:33 PM
To: Bigler, Jeff
Cc: Wathen, John
Subject: Follow-up from May 15 FDA-EPA fish advice meeting

Hi Jeff,

Sorry you missed the meeting this week. It was a productive one. Sharon mentioned there were some late comments and wanted to make sure our comment response table captured those. I thought they did, but wanted to make sure. In particular, she wanted to know if the one from Healthy Mothers, Healthy Babies that discussed fetus vs. unborn child made it in. Can you please check on that?

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]
From: Larimer, Lisa
Sent: Tue 5/19/2015 1:48:20 PM
Subject: FW: Follow-up from May 15 FDA-EPA fish advice meeting

Hi Sharon,

Late comments did made it into the comment response table. Here's what was captured from the Healthy Mothers, Healthy Babies submittal.

-Lisa

From: Bigler, Jeff
Sent: Monday, May 18, 2015 10:04 AM
To: Larimer, Lisa
Cc: Wathen, John
Subject: RE: Follow-up from May 15 FDA-EPA fish advice meeting

Here are the comments that were included from Healthy Mothers, Healthy Babies (#214) related to the fetus. There are other comments from them regarding language (e.g., servings instead of ounces)

Response to Comments table:

Page 4, "Provide more information on the benefits of eating fish while pregnant, such as the development it supports in the fetus, and more specifically what the dangers are in not getting enough of the fatty acids (D202, D0214, D0221, D0213, D0219, D0138, D0227, 0097, 0095,)" and "Stress that there is evidence showing moderate levels of fish consumption has a significant and positive effect on a fetus/child's IQ (D0206, D0214, D0219)"

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Page 18, "The new advice retains the recommendation that expecting moms should "limit white (albacore) tuna to 6 ounces a week." However, according to data in your net effects report which evaluates the benefits of seafood at the species level [A Quantitative Assessment of the Net Effects on Fetal Neurodevelopment From Eating Commercial Fish (As Measured by IQ and also by Early Age Verbal Development in Children, available at: http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm393211.htm], pregnant women can safely consume up to 67 ounces of canned albacore tuna per week - that's 33 servings per week and more than 11 times the limit you are proposing to recommend. This recommendation is not scientifically justified. (FDA-2014-N-0595-0047/FDA-2014-N-0595-0049, similar comments in FDA-2014-N-0595-0097, FDA-2014-N-0595-DRAFT-0206, FDA-2014-N-0595-DRAFT-0214, FDA-2014-N-0595-DRAFT-0217, FDA-2014-N-0595-DRAFT-0218, FDA-2014-N-0595-DRAFT-0221, FDA-2014-N-0595-DRAFT-0227, FDA-2014-N-0595-DRAFT-0232) "

Page 25, "The advisory might be more effective if there is more information on the benefits of eating fish while pregnant, such as the development it supports in the fetus, and more specifically what the dangers are in not getting enough of the fatty acids (FDA-2014-N-0595-DRAFT-0110). Benefits to highlight include cardiovascular health for mothers and neurodevelopmental and eye benefits to children (FDA-2014-N-0595-DRAFT-0202, FDA-2014-N-0595-DRAFT-0214, FDA-2014-N-0595-DRAFT-0221). It is important to explain to women why seafood intake in the childbearing years is the best advice we can give for their current and future health, and the development of their infants. This advice will empower women to choose seafood intake on a regular basis. (FDA-2014-N-0595-DRAFT-0213, FDA-2014-N-0595-DRAFT-0219)"

Page 42, "The message to the public should stress that there is evidence showing moderate levels of fish consumption has a significant and positive effect on a fetus/child's IQ. More women would heed this advice and attain benefits for themselves and their children if the overall message was more positive and encouraging- shift to positive framing. (FDA-2014-N-0595-DRAFT-0206, FDA-2014-N-0595-DRAFT-0214, FDA-2014-N-0595-DRAFT-0219)"

From: Larimer, Lisa

Sent: Thursday, May 14, 2015 1:33 PM
To: Bigler, Jeff
Cc: Wathen, John
Subject: Follow-up from May 15 FDA-EPA fish advice meeting

Hi Jeff,

Sorry you missed the meeting this week. It was a productive one. Sharon mentioned there were some late comments and wanted to make sure our comment response table captured those. I thought they did, but wanted to make sure. In particular, she wanted to know if the one from Healthy Mothers, Healthy Babies that discussed fetus vs. unborn child made it in. Can you please check on that?

Thanks,

Lisa

Lisa Larimer, P.E.

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]; Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Fri 8/28/2015 6:20:23 PM
Subject: Fw: Meeting request materials for fish advice

From: Penman, Crystal
Sent: Friday, August 28, 2015 12:38 PM
To: Bethel, Heidi
Cc: Ruf, Christine; Klasen, Matthew; Larimer, Lisa; Conerly, Octavia
Subject: RE: Meeting request materials for fish advice

Sent to scheduling.

From: Bethel, Heidi
Sent: Thursday, August 27, 2015 6:24 PM
To: Penman, Crystal
Cc: Ruf, Christine; Klasen, Matthew; Larimer, Lisa; Conerly, Octavia
Subject: Fwd: Meeting request materials for fish advice

Forwarding to Crystal for processing on Friday. Does Ken need an update on the USDA/ HHS meeting before Admin meeting? I am on annual leave so I have not reviewed these materials. Just keeping it moving.

Heidi

Sent from my iPhone

Begin forwarded message:

> **From:** "Larimer, Lisa" <Larimer.Lisa@epa.gov>
> **Date:** August 27, 2015 at 5:35:05 PM EDT
> **To:** "Bethel, Heidi" <Bethel.Heidi@epa.gov>, "Conerly, Octavia" <Conerly.Octavia@epa.gov>, "Klasen, Matthew" <Klasen.Matthew@epa.gov>
> **Subject: Meeting request materials for fish advice**
>
> We finally met with HHS and USDA on the confluence of our fish advice with their Dietary Guidelines for Americans and we are good to go. Here are the meeting request and memo for the briefing for the Administrator.

FYI, I won't be in the office tomorrow through Labor Day. John will be in the office tomorrow morning, but then out until Sept. 10. Hopefully you won't have any questions. If you do and can't reach us, try Samantha Fontenelle.

Thanks!

Lisa

Cc: Wathen, John[Wathen.John@epa.gov]
To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Fri 8/28/2015 2:26:35 PM
Subject: Fw: Meeting request materials for fish advice
Admin mtg request FDA-EPA fish advice.docx
Briefing Memo FDA-EPA fish advice.docx

Octavia, Heidi and Matt were all out of the office, but Heidi was checking email and sent the stuff to Crystal to process and forwarded to Lynn while Octavia is out. Making sure you two have the materials in case anything comes up. Will probably be offline for most of the rest of the day now. See you in September!

-Lisa

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 5:35 PM
To: Bethel, Heidi; Conerly, Octavia; Klasen, Matthew
Subject: Meeting request materials for fish advice

We finally met with HHS and USDA on the confluence of our fish advice with their Dietary Guidelines for Americans and we are good to go. Here are the meeting request and memo for the briefing for the Administrator.

FYI, I won't be in the office tomorrow through Labor Day. John will be in the office tomorrow morning, but then out until Sept. 10. Hopefully you won't have any questions. If you do and can't reach us, try Samantha Fontenelle.

Thanks!

Lisa

To: Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Larimer, Lisa
Sent: Fri 8/28/2015 2:21:31 PM
Subject: Re: Meeting request materials for fish advice

Yes, John Wathen. Sorry, I was rushing yesterday. Late to kid pick-up.

From: Bethel, Heidi
Sent: Thursday, August 27, 2015 6:28 PM
To: Larimer, Lisa
Cc: Conerly, Octavia; Klasen, Matthew; Penman, Crystal; Ruf, Christine
Subject: Re: Meeting request materials for fish advice

Who is John? John Wathen?

Sent from my iPhone

On Aug 27, 2015, at 5:35 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

> We finally met with HHS and USDA on the confluence of our fish advice with their Dietary Guidelines for Americans and we are good to go. Here are the meeting request and memo for the briefing for the Administrator.
>
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>
> Thanks!
>
> Lisa

<Admin mtg request FDA-EPA fish advice.docx>

<Briefing Memo FDA-EPA fish advice.docx>

To: Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Larimer, Lisa
Sent: Fri 8/28/2015 2:20:53 PM
Subject: Re: Meeting request materials for fish advice

He should get a verbal update at today's staff meeting.

From: Bethel, Heidi
Sent: Thursday, August 27, 2015 6:24 PM
To: Penman, Crystal
Cc: Ruf, Christine; Klasen, Matthew; Larimer, Lisa; Conerly, Octavia
Subject: Fwd: Meeting request materials for fish advice

Forwarding to Crystal for processing on Friday. Does Ken need an update on the USDA/ HHS meeting before Admin meeting? I am on annual leave so I have not reviewed these materials. Just keeping it moving.

Heidi

Sent from my iPhone

Begin forwarded message:

From: "Larimer, Lisa" <Larimer.Lisa@epa.gov>
Date: August 27, 2015 at 5:35:05 PM EDT
To: "Bethel, Heidi" <Bethel.Heidi@epa.gov>, "Conerly, Octavia" <Conerly.Octavia@epa.gov>, "Klasen, Matthew" <Klasen.Matthew@epa.gov>
Subject: Meeting request materials for fish advice

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FYI, I won't be in the office tomorrow through Labor Day. John will be in the office tomorrow morning, but then out until Sept. 10. Hopefully you won't have any questions. If you do and can't reach us, try Samantha Fontenelle.

Thanks!

Lisa

To: Fabiano, Claudia[Fabiano.Claudia@epa.gov]; McRae, Evelyn[McRae.Evelyn@epa.gov]; Buffo, Corey[Buffo.Corey@epa.gov]; Barash, Shari[Barash.Shari@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Wilcut, Lars[Wilcut.Lars@epa.gov]; Vlcan, Manjali[Vlcan.Manjali@epa.gov]; Kramer, Bill[Kramer.Bill@epa.gov]
Cc: Washington, Evelyn[Washington.Evelyn@epa.gov]
From: Larimer, Lisa
Sent: Thur 5/14/2015 3:20:54 PM
Subject: RE: Items for SHM and BS biweekly

Since I won't be there, please share these details with Sara.

FDA-EPA fish advice

- Meeting w/ FDA yesterday at College Park went very well.
- Q&As are almost final; we are still tweaking the chart.
- Response to comments is well under way.
- Next meeting will be mid-June. Will need at least one more face-to-face meeting after that before all materials will be ready for management review – projecting July.

From: Fabiano, Claudia
Sent: Thursday, May 14, 2015 9:39 AM
To: McRae, Evelyn; Buffo, Corey; Larimer, Lisa; Barash, Shari; Wathen, John; Wilcut, Lars; Vlcan, Manjali; Kramer, Bill
Cc: Washington, Evelyn
Subject: RE: Items for SHM and BS biweekly

Latest status on 3rd Maine action letter

From: McRae, Evelyn
Sent: Thursday, May 14, 2015 8:28 AM
To: Buffo, Corey; Fabiano, Claudia; Larimer, Lisa; Barash, Shari; Wathen, John; Wilcut, Lars; Vlcan, Manjali; Kramer, Bill
Cc: Washington, Evelyn; McRae, Evelyn
Subject: Items for SHM and BS biweekly

Please send any additional items, by 12 noon, for Sara and Betsy biweekly scheduled for today (5/14/2015 at 3:00pm). The below is what I have thus far:

- WQS and OMB Discussion
- Region 6 and State Review of Draft Decisions documents
- May 20th SHPD Leadership Retreat
- Personnel

Thanks, Evelyn M. 202.566.1018

To: Hisel-Mccoy, Sara[Hisel-McCoy.Sara@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]; Shari Barash[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Wed 4/22/2015 8:30:55 PM
Subject: Summary of 4/22/15 FDA-EPA meeting on fish advice

Sara,

We had another productive meeting with FDA today:

Ex. 5 - Deliberative Process

Our next meeting is May 13, v **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]; Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]; Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Spungen, Judith[Judith.Spungen@fda.hhs.gov]; Naidenko, Olga[Naidenko.Olga@epa.gov]
From: Larimer, Lisa
Sent: Wed 4/22/2015 7:52:40 PM
Subject: Summary of 4/22/15 FDA-EPA meeting on fish advice & next steps

Hi everyone,

Here's a synopsis of today's meeting:

Ex. 5 - Deliberative Process

Next steps:

Ex. 5 - Deliberative Process

- □□□□□□□ Group will meet again on May 13 **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Decisions we still need to make:

•□□□□□□□ Location of next meeting – any preference? Three people have to travel regardless of location.

•□□□□□□□ How to divvy up the Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Please add anything I may have missed.

Lisa Larimer, P.E.

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Berger, Martha[Berger.Martha@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 7/28/2015 2:58:10 PM
Subject: Requesting an informal meeting on FDA-EPA updated fish advice
Fish advice-results of CHPAC recommendations.xlsx
Fish Advice Qs and As-070915.docx
FISH_CHART_H_7.18.pdf
FISH_CHART_V_7.18.pdf

Martha,

We in the Office of Science and Technology would love to update you on what the final version of the FDA-EPA fish advice is looking like and how CHPAC's recommendations were addressed. In an ideal world, we'd like to meet with Ruth Etzel and whichever staff are interested in this project before we brief our AA on Thursday afternoon. Whatever magic you can work on your end would be much appreciated.

Here are some relevant files in case people want to take a look before the meeting.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

Cc: Keating, Jim[Keating.Jim@epa.gov]; Fabiano, Claudia[Fabiano.Claudia@epa.gov]
To: Buffo, Corey[Buffo.Corey@epa.gov]; Barash, Shari[Barash.Shari@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Mon 7/27/2015 12:38:31 PM
Subject: Lisa out today - sick kids

One has strep, the other a full blown cold & hopefully not a sinus infection. I don't have anything that can't wait until tomorrow. I've got a presentation ready for Ken on Thursday.

Question for folks who have briefed Ken more recently than I, given his predilection for wordsmithing:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Here are the pieces we'll be going public with:

- chart with advice

- Qs & As

- response to comments document

- text for technical web page

- notice for Federal Register

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Larimer, Lisa
Sent: Thur 7/23/2015 3:17:30 PM
Subject: RE: technical appendix
technical web page-fish advice-072315.docx

I incorporated the note Ex. 5 - Deliberative Process into the main text instead of a footnote. It fit well.

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, July 23, 2015 10:59 AM
To: Larimer, Lisa
Subject: technical appendix

Hi,

Can you please send us the most recent technical appendix? Were you going to add a footnote Ex. 5 - Deliberative Process Are there any other changes? I will be on leave Friday (but checking email) and all next week—so trying to wrap things up.

debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 7/22/2015 10:00:12 PM
Subject: RE: FDA-EPA Fish Advice 7 v1.pptx

Betsy said she didn't need a briefing since we've kept her in the loop throughout the process. We met with the Office of Science Policy today and that went well. We expect to get the green light from them early next week. I'm still trying to schedule a time with the Office of Children's Health Protection…. We brief our Assistant Administrator next Thursday, July 30. Administrator briefing hasn't been scheduled yet; we have to wait until after we meet with the AA.

Glad to hear it went well!

-Lisa

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Wednesday, July 22, 2015 5:49 PM
To: Larimer, Lisa; Jones, William; Smegal, Deborah
Subject: RE: FDA-EPA Fish Advice 7 v1.pptx
Importance: High

It went extremely well – our Deputy Commissioner and Center director both blessed it!

Deb is making a few minor edits to the FR notice – it turns out when we made changes to the advice we didn't get those changes updated in the FR notice and she found a couple of other small things

I'm going to have the designer modify the hands so the fish in the palm pops more.

When are you guys presenting to Betsy? What about your Administrator?

Sharon

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, July 22, 2015 5:20 PM
To: Natanblut, Sharon; Jones, William; Smegal, Deborah
Subject: RE: FDA-EPA Fish Advice 7 v1.pptx

Thank you! Hope your briefing went well today.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, July 21, 2015 5:34 PM
To: Jones, William; Smegal, Deborah; Larimer, Lisa
Subject: FDA-EPA Fish Advice 7 v1.pptx

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 7/21/2015 8:36:09 PM
Subject: FW: Corrections needed on fish advice chart
FISH_CHART_H_7.18.pdf
FISH_CHART_V_7.18.pdf

Here are the almost final versions of the chart Ex. 5 - Deliberative Process Can you print them out in color for our meeting with Bob?

Thanks!

From: Kevin Grady [mailto: Ex. 6 - Personal Privacy
Sent: Saturday, July 18, 2015 2:18 PM
To: Natanblut, Sharon
Cc: Larimer, Lisa
Subject: Re: Corrections needed on fish advice chart

Hi Sharon and Lisa,

Here are the two fish charts with Lisa's corrections.

Talk soon,

Kevin

On Fri, Jul 17, 2015 at 5:07 PM, Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov> wrote:

> Thanks.
>
> Kevin - can you make these corrections this weekend?

Thanks.
Sharon

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Friday, July 17, 2015 5:06 PM
To: Natanblut, Sharon
Subject: Corrections needed on fish advice chart

Hi Sharon,

I took a quick glance at the vertical chart and noticed a few things:

Ex. 5 - Deliberative Process

* Pacific chub mackerel should be EL not AL

* Patagonian toothfish is missing the "h" at the end

Have a great weekend!

Lisa Larimer, P.E. | Team Leader
U.S. Environmental Protection Agency | Washington, DC
Office of Water | Standards and Health Protection Division
* (202) 566-1017 | * larimer.lisa@epa.gov<mailto:larimer.lisa@epa.gov>

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
Cc: Kevin Grady[Ex. 6 - Personal Privacy
From: Larimer, Lisa
Sent: Tue 7/21/2015 5:48:50 PM
Subject: RE: Corrections needed on fish advice chart

No, nothing else. Debbie and I found the same one.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, July 21, 2015 1:47 PM
To: Larimer, Lisa; Smegal, Deborah
Cc: Kevin Grady
Subject: RE: Corrections needed on fish advice chart

Lisa,

Any other changes? I think Deb raised one? I'd rather we not have to ask Kevin to go and do changes one at a time.

Thanks.

Sharon

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, July 21, 2015 1:40 PM
To: Kevin Grady; Natanblut, Sharon
Subject: RE: Corrections needed on fish advice chart

I hate to mention this, but **Ex. 5 - Deliberative Process**

From: Kevin Grady [mailto: Ex. 6 - Personal Privacy
Sent: Saturday, July 18, 2015 2:18 PM
To: Natanblut, Sharon
Cc: Larimer, Lisa
Subject: Re: Corrections needed on fish advice chart

Hi Sharon and Lisa,

Here are the two fish charts with Lisa's corrections.

Talk soon,

Kevin

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> Thanks.
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> Kevin - can you make these corrections this weekend?
> Thanks.
> Sharon
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Ex. 5 - Deliberative Process

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Lisa Larimer, P.E. | Team Leader
U.S. Environmental Protection Agency | Washington, DC
Office of Water | Standards and Health Protection Division
* (202) 566-1017 | * larimer.lisa@epa.gov<mailto:larimer.lisa@epa.gov>

To: Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Larimer, Lisa
Sent: Tue 7/21/2015 4:22:19 PM
Subject: FW: technical page
technical page-fish advice-072015.docx

I was rushing to get something to Debbie yesterday before I left. If you like, take a look and let me know what you think. This is suggested text for our "technical web page" where we go into more detail on how we came up with our chart.

From: Larimer, Lisa
Sent: Monday, July 20, 2015 6:28 PM
To: 'Smegal, Deborah'
Subject: RE: technical page

Let me know what you think. I still need to doublecheck the final fish names / formats.

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Monday, July 20, 2015 8:34 AM
To: Larimer, Lisa
Subject: technical page

Hi,

Can you please send the page with the technical information. I am not sure I have seen this yet, and Sharon mentioned that we need to have it for our briefing this week (Wedsnesday).

Thanks

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: 'Natanblut, Sharon'[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 4/21/2015 6:15:27 PM
Subject: 3rd FDA-EPA meeting on fish advice: proposed agenda & EPA edits to Q&As
draft advice and QA-042115-EPA edits.docx
Proposed Agenda-042215 FDA-EPA mtg.docx

Hi everyone,

Here is a proposed agenda and a copy of our full set of edits to the Q&As so you can see it before the meeting if you have time. If you have yours ready to share, we'd appreciate seeing them too.

Question about logistics: Does someone need to meet us at the door? I'm assuming we're meeting in the building at the corner of River Road and Paint Brush Parkway; please let me know if I'm incorrect. (I've never been there.) Can you provide the phone number of a contact person in case one of us is running late?

Proposed agenda

8:30-8:45 Review of agenda

8:45-9:00 Review of draft advice

9:00-9:30 Draft mock-ups of advice

9:30 – 10:00 Draft mock-ups of fish chart

10:00 – 10:15 Break

10:45 – 12:15 Revisions to Q&As

12:15-12:30 Next steps

See you tomorrow!

Lisa Larimer, P.E.

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

Proposed Agenda

Third FDA-EPA Meeting on Advice for Mercury Concentrations in Fish
Wednesday, April 22

8:30-8:45	Review of agenda
8:45-9:00	Review of draft advice
9:00-9:30	Draft mock-ups of advice
9:30 – 10:00	Draft mock-up of fish chart
10:00 – 10:15	Break
10:45 – 12:15	Revisions to Q&As
12:15-12:30	Next Steps

To: denise.hughes@fda.hhs.gov[denise.hughes@fda.hhs.gov]
From: Larimer, Lisa
Sent: Tue 4/21/2015 4:26:01 PM
Subject: RE: 3rd FDA-EPA meeting on fish advice

Thanks, Denise. You had alerted me earlier that there might be conflicts. He isn't an essential participant for this particular meeting, so I'll have someone from his staff update him afterward.

Thanks,
Lisa

-----Original Appointment-----
From: Hughes, Denise Y [mailto:Denise.Hughes@fda.hhs.gov] **On Behalf Of** Elkin, Ted
Sent: Tuesday, April 21, 2015 11:22 AM
To: Larimer, Lisa
Subject: Declined: 3rd FDA-EPA meeting on fish advice
When: Wednesday, April 22, 2015 8:30 AM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: FDA (College Park), Room 2E-032 in the CFSAN Wiley building

Good Morning Lisa:

Due to several meetings conflicts on Ted Elkin's schedule on 4/22/15, he will not attend the 3rd FDA-EPA Meeting on Fish Advice.

Thanks for your understanding.

Denise Y. Hughes
Executive Assistant to the Deputy Director
for Regulatory Affair
Office of the Center Director
Center for Food Safety and
Applied Nutrition
Phone: 240-402-2435 (direct line)
240-402-1600 (office)
301-436-2668 (fax)

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Wed 6/29/2016 3:29:36 PM
Subject: RE: documents for peer review
Ex. 5 - Deliberative Process

Here it is, Debbie. Should we keep or drop Ex. 5 - Deliberative Process

From: Larimer, Lisa
Sent: Wednesday, June 29, 2016 10:42 AM
To: 'Smegal, Deborah' <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: documents for peer review

Were we going to include Ex. 5 - Deliberative Process

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Wednesday, June 29, 2016 10:23 AM
To: Jones, William <William.Jones@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: documents for peer review

Hi,

Here are the documents for the peer review package.

Ex. 5 - Deliberative Process

Please let me know if you have any comments/suggestions/edits etc by COB today or sooner. Feel free to edit the peer review plan.

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Robiou, Grace[Robiou.Grace@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Naidenko, Olga[Naidenko.Olga@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Carrington, Clark D[Clark.Carrington@fda.hhs.gov]; 'Natanblut, Sharon'[Sharon.Natanblut@fda.hhs.gov]; 'William.jones@fda.hhs.gov'['William.jones@fda.hhs.gov']; 'Deborah.smegal@fda.hhs.gov'['Deborah.smegal@fda.hhs.gov']; 'Elkin, Ted'[Ted.Elkin@fda.hhs.gov]
From: Larimer, Lisa
Sent: Tue 4/14/2015 8:59:38 PM
Subject: RE: Materials resulting from Second FDA-EPA Meeting on Fish Advice
Fish advice chart-041415.xlsx

When I was closing files, the fish chart asked me if I wanted to save, so I'm not sure if the version I sent earlier incorporated all changes. Please use this one, just in case.

Thanks,
Lisa

From: Larimer, Lisa
Sent: Tuesday, April 14, 2015 4:44 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: Materials resulting from Second FDA-EPA Meeting on Fish Advice

Here are the chart and the revised advice/Q&As.
<< File: draft advice from Sharon-revised at 041415 mtg.docx >> << File: Fish advice chart-041415.xlsx >>

-----Original Appointment-----
From: Robiou, Grace
Sent: Tuesday, March 17, 2015 3:31 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Larimer, Lisa; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: Second FDA-EPA Meeting on Fish Advice
When: Tuesday, April 14, 2015 9:00 AM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest6105AAssateague/DC-EPA-West-OST

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Mon 4/13/2015 7:55:23 PM
Subject: Please print 8 color copies
Handout 2 Fish advice chart-041315.xlsx

Thanks!

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Robiou, Grace[Robiou.Grace@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Naidenko, Olga[Naidenko.Olga@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Carrington, Clark D[Clark.Carrington@fda.hhs.gov]; 'Natanblut, Sharon'[Sharon.Natanblut@fda.hhs.gov]; 'William.jones@fda.hhs.gov'['William.jones@fda.hhs.gov']; 'Deborah.smegal@fda.hhs.gov'['Deborah.smegal@fda.hhs.gov']; 'Elkin, Ted'[Ted.Elkin@fda.hhs.gov]
From: Larimer, Lisa
Sent: Mon 4/13/2015 5:04:46 PM
Subject: RE: Second FDA-EPA Meeting on Fish Advice
Agenda-Fish Advice-041415 FDA-EPA mtg.docx
Handout 2 Fish advice chart-041315.xlsx
Handout 5 Annotated QA-040715.docx
Handout 6 Table of Synthesized Comments-040715.docx
Handout 1 Summary of All Public Comments on Advice-040715.docx

Hi everyone. Here is the agenda and handouts 1, 2, 5 and 6 for tomorrow's meeting.
[Sharon, if you bring or send the electronic file with the projected mark-ups to the advice, I can project it on the big screen.]

Logistics:
Enter through the EPA West entrance at 1301 Constitution Ave, NW (same one as before) - Federal Triangle metro stop.
Call John Wathen at 202-566-0367 to lead you up.
Meeting will be in 6105A.
Call-in number is **Ex. 6 - Personal Privacy**

We look forward to seeing you! We have a jam-packed agenda.

Lisa Larimer, P.E.
U.S. Environmental Protection Agency | Washington, DC
Office of Water | Standards and Health Protection Division
☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

-----Original Appointment-----
From: Robiou, Grace
Sent: Tuesday, March 17, 2015 3:31 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Larimer, Lisa; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: Second FDA-EPA Meeting on Fish Advice
When: Tuesday, April 14, 2015 9:00 AM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest6105AAssateague/DC-EPA-West-OST

Agenda

Second FDA-EPA Meeting on Fish Advice for Pregnant/Nursing Women and Children
Tuesday, April 14

9:00-9:15 Welcome and Review of Agenda (Grace)

9:15 – 9:30 Verbal Summary of Public Comments that came in at end of comment period (Westat)
Handout #1: Final Summary of Comments document (not for public release)

9:30 – 10:30 Fish Chart (Lisa)
Handout #2: Fish Advice Chart, version dated 04/13/15
Discussion Topics:

a.
b.
c.
d.
e.
f.

Ex. 5 - Deliberative Process

10:30 – 10:45 Break

10:45 – 11:30 Fish Chart, continuation

11:30 – 12:15 Chart Mock-ups (Sharon)
Handout #3: Design options

12:15 – 1:15 Lunch

1:15 – 2:45 Revisions to Advice (Sharon)
Handout #4: Red-line strikeout of advice

2:45 – 3:00 Break

3:00 – 4:00 Qs and As (Sharon)
Handout #5: Annotated Qs and As

4:00 Next Steps
Handout #6: Table for Response of Comments (for public release)

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Larimer, Lisa
Sent: Thur 4/9/2015 8:36:51 PM
Subject: FW: Ex. 5 - Deliberative Process

Hi Deborah,

You were supposed to have been cced on this, but my computer is having severe issues today.

From: Larimer, Lisa
Sent: Thursday, April 09, 2015 2:58 PM
To: 'Carrington, Clark D'
Cc: Bigler, Jeff; Wathen, John
Subject: Ex. 5 - Deliberative Process

Clark-

Since you're heading off for jolly ol' England soon, we'd really like to benefit from your expertise before you go. Ideally **we would like to** Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process **before the 4/14 meeting**, but definitely before you leave. I know it seems like a lot, but I think the priorities would be for #1 & #5.

1. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

2.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

3. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

4. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

5. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

6. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

7. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Thanks,

Lisa

Cc: Bigler, Jeff[Bigler.Jeff@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Naidenko, Olga[Naidenko.Olga@epa.gov]
To: Robiou, Grace[Robiou.Grace@epa.gov]; William.jones@fda.hhs.gov[William.Jones@fda.hhs.gov]; 'Carrington, Clark D'[Clark.Carrington@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; 'Natanblut, Sharon'[Sharon.Natanblut@fda.hhs.gov]; 'Elkin, Ted'[Ted.Elkin@fda.hhs.gov]
From: Larimer, Lisa
Sent: Thur 4/9/2015 5:02:15 PM
Subject: Proposed agenda & other info for April 14 FDA-EPA meeting on fish advice
Proposed Agenda-041415 FDA-EPA mtg.docx
Ex. 5 - Deliberative Process for advisory-040715.xlsx
Summary of All Public Comments on Advice 20150407 - Final.docx

Hi everyone,

We here at EPA are looking forward to meeting with our FDA colleagues next week. In preparation for that, I am sending a proposed agenda (also copied into the email below for ease of responding with suggested changes), the final version of our internal summary of all comments received, and the latest version of the "fish chart" showing

Ex. 5 - Deliberative Process

Please let me know if you have any suggested additions or changes to the proposed agenda. See you next week!

-Lisa

Proposed Agenda

Second FDA-EPA Meeting on Advice for Mercury Concentrations in Fish
Tuesday, April 14

9:00-9:15 Welcome and Review of Today's Agenda (Grace)

9:15 – 9:30 Verbal Summary of Public Comments that came in at end of Comment period (Westat)
Handout #1: Final Summary of Comments document (not for public release)

9:30 – 10:30 Fish Chart (Lisa)
Handout #2: Chart, Version dated 4/XX/15
Discussion Topics:

Ex. 5 - Deliberative Process

10:30 – 10:45 Break

10:45 – 11:30 Fish Chart, continuation

11:30 – 12:15 Chart Mock ups (Sharon)
Handout #3: Design options

12:15 – 1:15 Lunch

1:15 – 2:45 Revisions to Advice (Sharon)
Handout #4: Red-line strike out

2:45 – 3:00 Break

3:00 – 4:00 Qs and As (Sharon)
Handout #5: Annotated Qs and As Ex. 5 - Deliberative Process

4:00 Next Steps
Handout #6: Table for Response of Comments (for public release)

Proposed Agenda

Second FDA-EPA Meeting on Advice for Mercury Concentrations in Fish
Tuesday, April 14

9:00-9:15 Welcome and Review of Today's Agenda (Grace)

9:15 – 9:30 Verbal Summary of Public Comments that came in at end of Comment period (Westat)
Handout #1: Final Summary of Comments document (not for public release)

9:30 – 10:30 Fish Chart (Lisa)
Handout #2: Chart, Version dated XX/YY/ZZ
Discussion Topics:
a.
b.
c.
d.
e.
f.

Ex. 5 - Deliberative Process

10:30 – 10:45 Break

10:45 – 11:30 Fish Chart, continuation

11:30 – 12:15 Chart Mock ups (Sharon)
Handout #3: Design options

12:15 – 1:15 Lunch

1:15 – 2:45 Revisions to Advice (Sharon)
Handout #4: Red-line strike out

2:45 – 3:00 Break

3:00 – 4:00 Qs and As (Sharon)
Handout #5: Annotated Qs and As from Westat

4:00 Next Steps
Handout #6: Table for Response of Comments (for public release)

To: Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 6/29/2016 2:17:03 PM
Subject: fish advice charge questions
Revised Peer Review Charge_4-14-16_final.docx
ATT00001.htm

From: Southerland, Elizabeth
Sent: Friday, June 17, 2016 1:14 PM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Fwd: Final Seafood Advice

Send me any comments by Monday so I can get back to Joel.

Sent from my iPhone

Begin forwarded message:

From: "Beauvais, Joel" <Beauvais.Joel@epa.gov>
Date: June 17, 2016 at 12:33:14 PM EDT
To: "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Cc: "Campbell, Ann" <Campbell.Ann@epa.gov>
Subject: FW: Final Seafood Advice

Hi, Betsy – Can I get your input on this **Ex. 5 - Deliberative Process** ?

Joel

From: Sharp, Jeremy [mailto:Jeremy.Sharp@fda.hhs.gov]
Sent: Friday, June 17, 2016 12:09 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Subject: Final Seafood Advice

Joel, I apologize for the long delay in my engagement of you on this. In our in-person meeting about Ex. 5 - Deliberative Process the FDA-EPA fish advice, you outlined 3 general areas of concern. We are most anxious to move forward to finalize the advice, and in the time since our meeting have worked to address and respond to your requests as noted below.

(1) **Messaging**: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

(2) **Data**: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

(3) **Peer review**: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process We look forward to hearing from you as soon as possible.

Jeremy Sharp

Deputy Commissioner

Policy, Planning, Legislation, and Analysis

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, Maryland 20993

301-796-8770

To: Jones, William[William.Jones@fda.hhs.gov]
From: Larimer, Lisa
Sent: Tue 6/28/2016 5:20:14 PM
Subject: RE: seafood advice!

Love it!

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Tuesday, June 28, 2016 1:07 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: seafood advice!

I'm a big fan and know it all-too-well. In fact, I was suggesting to someone earlier that maybe -

there wasn't going to be any fish advise after all:

https://www.youtube.com/watch?v=B3KBuQHHKx0

and that maybe we were in denial about its demise:

https://www.youtube.com/watch?v=4vuW6tQ0218

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, June 28, 2016 12:54 PM
To: Jones, William; Natanblut, Sharon; Smegal, Deborah; Wathen, John
Subject: RE: seafood advice!

Sounds great, Bill. It appears my refrain about the fish advice that I've been chanting for many months now is still a propos: it's not dead! From the incomparable Monty Python:

https://www.youtube.com/watch?v=Jdf5EXo6I68

It's a fairly long intro; you can safely skip the first 50 seconds if you like. And fair warning, it's a bit macabre.

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Tuesday, June 28, 2016 12:42 PM
To: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: seafood advice!

We still have the workgroup retreat/happy hour on the roof of my houseboat on the Washington Channel in the offing, just waiting for something to celebrate…and it's long overdue!

From: Natanblut, Sharon
Sent: Tuesday, June 28, 2016 12:23 PM
To: Smegal, Deborah; Jones, William; Larimer, Lisa; Wathen, John
Subject: RE: seafood advice!

Very exciting!!!

Lisa and John, **Ex. 5 - Deliberative Process** We'll have to go out for drinks.

From: Smegal, Deborah
Sent: Tuesday, June 28, 2016 12:16 PM
To: Natanblut, Sharon; Jones, William; Larimer, Lisa; Wathen, John
Subject: RE: seafood advice!

Hi,

OK Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Natanblut, Sharon
Sent: Tuesday, June 28, 2016 12:12 PM
To: Jones, William; Larimer, Lisa; Wathen, John
Cc: Smegal, Deborah
Subject: RE: seafood advice!

Ex. 5 - Deliberative Process Deb, is it possible to get an updated schedule Ex. 5 - Deliberative Process

From: Jones, William
Sent: Tuesday, June 28, 2016 12:06 PM
To: Larimer, Lisa; Wathen, John

Cc: Smegal, Deborah; Natanblut, Sharon
Subject: RE: seafood advice!

We just heard that **Ex. 5 - Deliberative Process**

From: Jones, William
Sent: Monday, June 27, 2016 3:13 PM
To: Natanblut, Sharon; Larimer, Lisa; Wathen, John
Cc: Smegal, Deborah
Subject: RE: seafood advice!

Sounds good!

From: Larimer, Lisa <Larimer.Lisa@epa.gov>
Date: June 27, 2016 at 3:03:39 PM EDT
To: Wathen, John <Wathen.John@epa.gov>, Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>, Jones, William <William.Jones@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: seafood advice!

Good sailing winds ahead! **Ex. 5 - Deliberative Process**
Ex. 5 - Deliberative Process

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Friday, June 24, 2016 10:05 AM
To: Wathen, John <Wathen.John@epa.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: seafood advice!

I like the sound of this…fingers are crossed.

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Friday, June 24, 2016 9:58 AM
To: Natanblut, Sharon; Larimer, Lisa
Cc: Smegal, Deborah; Jones, William
Subject: Re: seafood advice!

Ex. 5 - Deliberative Process

Keep your fingers crossed. Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

~John

From: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Sent: Thursday, June 23, 2016 5:21 PM
To: Larimer, Lisa; Wathen, John
Cc: Smegal, Deborah; Jones, William
Subject: seafood advice!

Hi guys,

We miss you!!! Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process Please let us know if you hear anything!!!

Sharon

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 6/28/2016 4:35:45 PM
Subject: RE: seafood advice!

Ex. 5 - Deliberative Process sounds great. So happy to be moving again.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, June 28, 2016 12:23 PM
To: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: seafood advice!

Very exciting!!!

Lisa and John, Ex. 5 - Deliberative Process We'll have to go out for drinks.

From: Smegal, Deborah
Sent: Tuesday, June 28, 2016 12:16 PM
To: Natanblut, Sharon; Jones, William; Larimer, Lisa; Wathen, John
Subject: RE: seafood advice!

Hi,

OK. Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Natanblut, Sharon
Sent: Tuesday, June 28, 2016 12:12 PM
To: Jones, William; Larimer, Lisa; Wathen, John
Cc: Smegal, Deborah
Subject: RE: seafood advice!

Ex. 5 - Deliberative Process Deb, is it possible to get an updated schedule **Ex. 5 - Deliberative Process**

From: Jones, William
Sent: Tuesday, June 28, 2016 12:06 PM
To: Larimer, Lisa; Wathen, John
Cc: Smegal, Deborah; Natanblut, Sharon
Subject: RE: seafood advice!

Ex. 5 - Deliberative Process

From: Jones, William
Sent: Monday, June 27, 2016 3:13 PM
To: Natanblut, Sharon; Larimer, Lisa; Wathen, John
Cc: Smegal, Deborah
Subject: RE: seafood advice!

Sounds good!

From: Larimer, Lisa <Larimer.Lisa@epa.gov>
Date: June 27, 2016 at 3:03:39 PM EDT
To: Wathen, John <Wathen.John@epa.gov>, Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>, Jones, William <William.Jones@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: seafood advice!

Good sailing winds ahead! **Ex. 5 - Deliberative Process**
Ex. 5 - Deliberative Process

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Friday, June 24, 2016 10:05 AM
To: Wathen, John <Wathen.John@epa.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: seafood advice!

I like the sound of this…fingers are crossed.

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Friday, June 24, 2016 9:58 AM
To: Natanblut, Sharon; Larimer, Lisa
Cc: Smegal, Deborah; Jones, William
Subject: Re: seafood advice!

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Keep your fingers crossed. Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

~John

From: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Sent: Thursday, June 23, 2016 5:21 PM
To: Larimer, Lisa; Wathen, John
Cc: Smegal, Deborah; Jones, William
Subject: seafood advice!

Hi guys,

We miss you!!! Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process Please let us know if you hear anything!!!

Sharon

To: Frey, Sharon[Frey.Sharon@epa.gov]
From: Larimer, Lisa
Sent: Mon 6/27/2016 8:44:52 PM
Subject: RE: EPA/FDA fish advice

Ex. 5 - Deliberative Process there will be a peer review, but I don't know if there will be a product that's made publicly available – is that what you're asking? Timing at this point would be a complete guess – perhaps mid-October?

From: Frey, Sharon
Sent: Monday, June 27, 2016 4:43 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: EPA/FDA fish advice

Will there be any type of peer review product (as opposed to the final fish advice) available? If so, when?

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Larimer, Lisa
Sent: Mon 6/20/2016 5:53:53 PM
Subject: RE: Final Seafood Advice

Betsy, that should be ok. I just have that one comment about Ex. 5 - Deliberative Process

From: Beauvais, Joel
Sent: Monday, June 20, 2016 1:53 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: Final Seafood Advice

Thanks, Betsy. You guys ok if I pass this email forward to Tom B and Kacee to engage them on this?

From: Southerland, Elizabeth
Sent: Monday, June 20, 2016 1:51 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Final Seafood Advice

We reviewed the revised draft charge from FDA (and corresponding email from Jeremy) and compared it to the version we sent to them in January (both versions are attached).

Overall we do not have any issues with FDA's changes to the charge to the peer reviewers.

For your information, we found the following changes:

Ex. 5 - Deliberative Process

Begin forwarded message:

From: "Beauvais, Joel" <Beauvais.Joel@epa.gov>
Date: June 17, 2016 at 12:33:14 PM EDT
To: "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Cc: "Campbell, Ann" <Campbell.Ann@epa.gov>
Subject: FW: Final Seafood Advice

Hi, Betsy – Can I get your input on this in advance of engaging with Tom B?

Joel

From: Sharp, Jeremy [mailto:Jeremy.Sharp@fda.hhs.gov]
Sent: Friday, June 17, 2016 12:09 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Subject: Final Seafood Advice

Joel, I apologize for the long delay in my engagement of you on this. In our in-person meeting about Ex. 5 - Deliberative Process the FDA-EPA fish advice, you outlined 3 general areas of concern. We are most anxious to move forward to finalize the advice, and in the time since our meeting have worked to address and respond to your

requests as noted below.

(1) **Messaging**: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

(2) **Data**: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

(3) **Peer review**: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process We look forward to hearing from you as soon as possible.

Jeremy Sharp

Deputy Commissioner

Policy, Planning, Legislation, and Analysis

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, Maryland 20993

301-796-8770

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Mon 6/20/2016 3:12:06 PM
Subject: Please review before I send

We reviewed the revised draft charge from FDA and compared it to Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process We found the following changes:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Southerland, Elizabeth
Sent: Friday, June 17, 2016 1:14 PM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Fwd: Final Seafood Advice

Send me any comments by Monday so I can get back to Joel.

Sent from my iPhone

Begin forwarded message:

From: "Beauvais, Joel" <Beauvais.Joel@epa.gov>

Date: June 17, 2016 at 12:33:14 PM EDT
To: "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Cc: "Campbell, Ann" <Campbell.Ann@epa.gov>
Subject: FW: Final Seafood Advice

Hi, Betsy – Can I get your input on this Ex. 5 - Deliberative Process ?

Joel

From: Sharp, Jeremy [mailto:Jeremy.Sharp@fda.hhs.gov]
Sent: Friday, June 17, 2016 12:09 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Subject: Final Seafood Advice

Joel, I apologize for the long delay in my engagement of you on this. In our in-person meeting about Ex. 5 - Deliberative Process the FDA-EPA fish advice, you outlined 3 general areas of concern. We are most anxious to move forward to finalize the advice, and in the time since our meeting have worked to address and respond to your requests as noted below.

(1) **Messaging**: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

(2) **Data**: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

(3) **Peer review**: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process We look forward to hearing from you as soon as possible.

Jeremy Sharp

Deputy Commissioner

Policy, Planning, Legislation, and Analysis

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, Maryland 20993

301-796-8770

To: Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]
From: Larimer, Lisa
Sent: Wed 4/20/2016 8:53:29 PM
Subject: At long last here's the technical appendix
technical web page-fish advice redline- 4 20 16 LL.docx

Sorry it took so long. By the way, I'm teleworking today if you want to call. Ex. 6 - Personal Privacy I haven't vetted it with anyone yet, but I doubt they would have issues.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

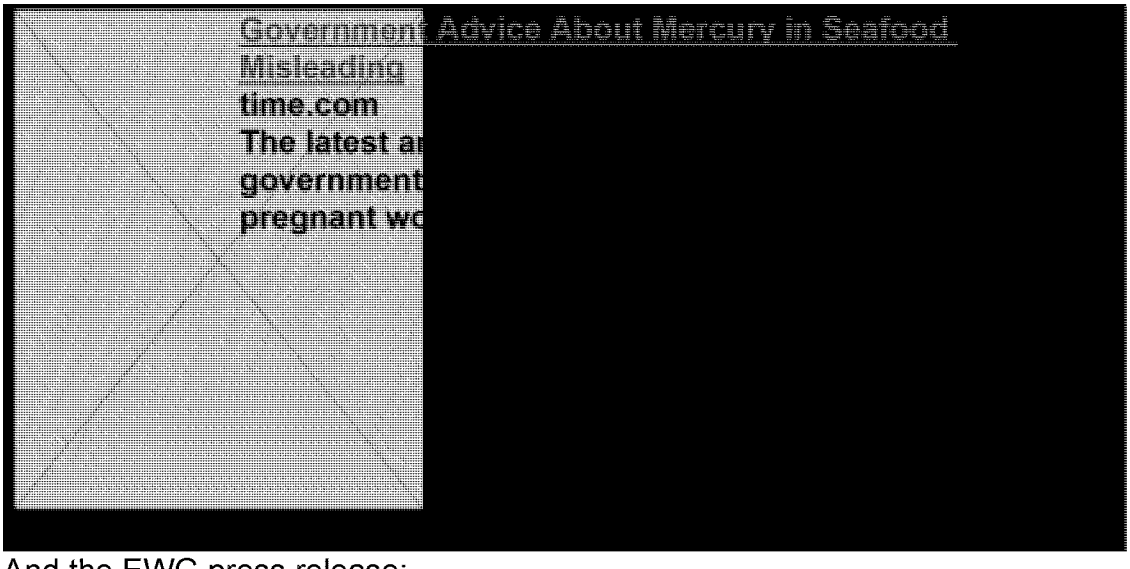
Cc: Wathen, John[Wathen.John@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]
To: Wilcut, Lars[Wilcut.Lars@epa.gov]; Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Wed 3/16/2016 2:08:07 PM
Subject: Re: Fish Mercury Article

It's not as bad as I thought it would be. Maybe it will push people to get our advice out.

From: Wilcut, Lars
Sent: Wednesday, March 16, 2016 8:23 AM
To: Barash, Shari; Larimer, Lisa
Subject: Fish Mercury Article

Just saw this:

http://time.com/4259955/government-warnings-about-mercury-in-fish-inadequate-report/



And the EWG press release:

http://www.ewg.org/release/seafood-advice-too-much-mercury-not-enough-healthy-fats

[redacted]

To: Kotwicki, Lauren[Lauren.Kotwicki@fda.hhs.gov]
From: Larimer, Lisa
Sent: Tue 3/15/2016 12:18:25 PM
Subject: Re: FDA/EPA Fish Advice Response to Time Magazine

Hi Lauren,

Nice to meet you, too. Thanks for sharing this with me. It looks fine (I recognize Sharon's work!). We also received an inquiry. I'll share our response once we have one.

-Lisa

From: Kotwicki, Lauren <Lauren.Kotwicki@fda.hhs.gov>
Sent: Monday, March 14, 2016 6:22 PM
To: Larimer, Lisa
Subject: FDA/EPA Fish Advice Response to Time Magazine

Hi Lisa,

My name is Lauren Kotwicki, I am a press officer at the FDA. We are responding to an inquiry from Time Magazine about Fish Advice and they reference FDA and EPA. We wanted to share our response with you, we still have to run it to the lawyers and the department, but I wanted to share with you right away. I'll let you know if there are any major changes.

Thank you and nice to meet you via email.

Reporter: Alice Park

Outlet: Time Magazine

Background: Reporter is a medicine writer at TIME and is working on a story about an upcoming report looking at mercury in fish.

1. **Which criteria did the FDA and EPA use to come up w/its list of high and low mercury fish?**

Ex. 5 - Deliberative Process

2. **The FDA and EPA draft recommendations currently list canned tuna as a low mercury fish. There is data to dispute that. On what criteria does the FDA and EPA base its decision to list canned tuna as a low mercury fish?**

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

3. Does the FDA or EPA have plans to revise this recommendation, particularly for pregnant women?

Ex. 5 - Deliberative Process

Lauren Kotwicki
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9549 / Cell: 202-906-0043
Lauren.Kotwicki@fda.hhs.gov

Cc: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
To: Jones, William[William.Jones@fda.hhs.gov]
From: Larimer, Lisa
Sent: Mon 3/14/2016 8:54:53 PM
Subject: Re: another comment on EWG report

Thanks, Bill. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process I'll get John right on it. Oh, John. . .

From: Jones, William <William.Jones@fda.hhs.gov>
Sent: Monday, March 14, 2016 4:51 PM
To: Larimer, Lisa
Cc: Smegal, Deborah; Natanblut, Sharon
Subject: RE: another comment on EWG report

Lisa – here is one thing you might want to look into:

The text from the EWG report references a Buchanan paper and reads:

"The Centers for Disease Control and Prevention regularly monitor mercury exposure for the American public. One CDC study found that one–fourth of women eating seafood two or more times per week had mercury concentrations in their blood above 3.5 micrograms per liter—a level that, if they were pregnant, would expose their developing fetus to too much mercury.[29]"

And here is that referenced paper (attached):

29. Susan Buchanan, et al. 2014. Methyl mercury exposure in populations at risk: Analysis of NHANES 2011–2012. Environmental Research. 140:56-64. Available: www.sciencedirect.com/science/article/pii/ S0013935115000766

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[redacted]

At first glance (Results section, p. 58) it does appear to be 5% overall, but 25% within an Asian subpopulation?

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Monday, March 14, 2016 3:56 PM
To: Natanblut, Sharon
Cc: Smegal, Deborah; Jones, William
Subject: Re: another comment on EWG report

Thanks, Sharon. NHANES data is definitely something we track, and EWG's numbers don't mesh with my recollection. We'll look into it.

-Lisa

From: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Sent: Monday, March 14, 2016 3:53 PM
To: Larimer, Lisa
Cc: Smegal, Deborah; Jones, William
Subject: FW: another comment on EWG report

Lisa,

Here's data from Deb,

Would be great for you guys to discuss.

Sharon

From: Smegal, Deborah
Sent: Monday, March 14, 2016 8:53 AM
To: Jones, William; Natanblut, Sharon
Subject: another comment on EWG report

Hi,

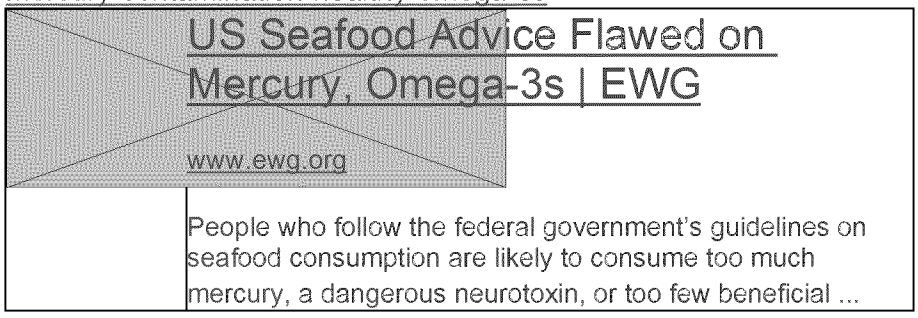
As a follow up we conclude that **only 5% women >3.5 ug/L** (mercury blood levels associated with the EPA RfD) based on the latest/ newest 2011-2012 NHANES. Therefore the EWG statement:

- 25-29% of women have mercury blood levels above the EPA RfD (> 3.5 ug/L blood or 1 ppm hair) is not verifiable based on the latest data.

Our team has reviewed the previous EWG comments and documents from the public comment period. **Ex. 5 - Deliberative Process** I have included 2 exerpts below:

The latest report from EWG is similar in many respects to their previous comments and reports.

http://www.ewg.org/research/us-gives-seafood-eaters-flawed-advice-on-mercury-contamination-healthy-omega-3s



EWG	2014	printed and highlighted. Critical of 2014 EPA/FDA advice for not being health protective, request precise, science based information for how to consume sufficient omega-3s while keeping mercury levels as low as possible. Ex. 5 - Deliberative Process **Ex. 5 - Deliberative Process** Ex. 5 - Deliberative Process THey use a 75 kg women Ex. 5 - Deliberative Process Statement that >10% women have mercury levels >3.5 ug/L is based on 1999-2004 NHANES data; newer 2011-2012 NHANES shows only 5%>3.5 ug/L
EWG-MPP	2014	http://www.ewg.org/research/five-things-fda-and-epa-didn-t-tell-you-about-seafood-safety FIVE THINGS FDA AND EPA DIDN'T TELL YOU ABOUT SEAFOOD SAFETY

printed and highlighted. Critical of 2014 EPA/FDA advice for not being health protective, especially for canned albacore tuna. **Ex. 5 - Deliberative Process** **Ex. 5 - Deliberative Process** **Ex. 5 - Deliberative Process** 10% of women of childbearing age above 5 ug/L is not current or verifiable; 2011-2012 NHANES shows 5% of females have mercury blood levels > 3.99 ug/L . Analysis by Buchannan et al. 2015 shows that 1.7% of women on child bearing age have blood mercury > 5.8 ug/L (RfD), while 5% > 3.6 ug/L.

Hope this helps.

Debbie

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Mon 3/14/2016 7:58:30 PM
Subject: Fw: another comment on EWG report

Hi John,

Thought you were on the email list here. Can you look into the NHANES angle? Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Larimer, Lisa
Sent: Monday, March 14, 2016 3:55 PM
To: Natanblut, Sharon
Cc: Smegal, Deborah; Jones, William
Subject: Re: another comment on EWG report

Thanks, Sharon. NHANES data is definitely something we track, and EWG's numbers don't mesh with my recollection. We'll look into it.

-Lisa

From: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Sent: Monday, March 14, 2016 3:53 PM
To: Larimer, Lisa
Cc: Smegal, Deborah; Jones, William
Subject: FW: another comment on EWG report

Lisa,

Here's data from Deb,

Would be great for you guys to discuss.

Sharon

From: Smegal, Deborah
Sent: Monday, March 14, 2016 8:53 AM
To: Jones, William; Natanblut, Sharon
Subject: another comment on EWG report

Hi,

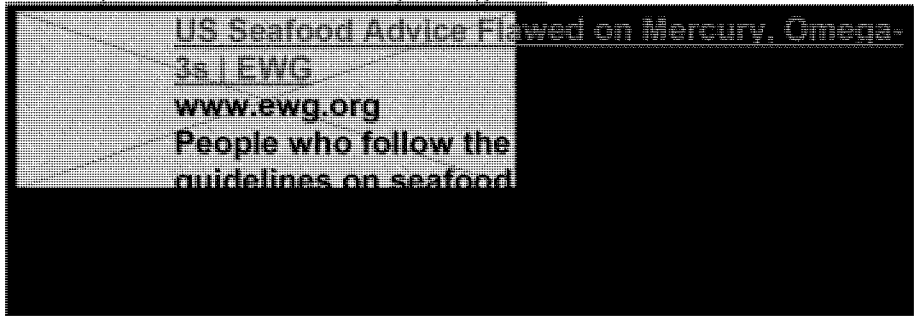
As a follow up we conclude that **only 5% women >3.5 ug/L** (mercury blood levels associated with the EPA RfD) based on the latest/ newest 2011-2012 NHANES. Therefore the EWG statement:

- 25-29% of women have mercury blood levels above the EPA RfD (> 3.5 ug/L blood or 1 ppm hair) is not verifiable based on the latest data.

Our team has reviewed the previous EWG comments and documents from the public comment period. **Ex. 5 - Deliberative Process** I have included 2 exerpts below:

The latest report from EWG is similar in many respects to their previous comments and reports.

http://www.ewg.org/research/us-gives-seafood-eaters-flawed-advice-on-mercury-contamination-healthy-omega-3s



EWG 2014 printed and highlighted. Critical of 2014 EPA/FDA advice for not being health protective, request precise, science based information for how to consume sufficient omega-3s while keeping mercury levels as low as possible. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process THey use a 75 kg women Ex. 5 - Deliberative Process

Statement that >10% women have mercury levels >3.5 ug/L is based on 1999-2004 NHANES data; newer 2011-2012 NHANES shows only 5%>3.5 ug/L

EWG-MPP	2014	http://www.ewg.org/research/five-things-fda-and-epa-didn-t-tell-you-about-seafood-safety	FIVE THINGS FDA AND EPA DIDN'T TELL YOU ABOUT SEAFOOD SAFETY

printed and highlighted. Critical of 2014 EPA/FDA advice for not being health protective, especially for canned albacore tuna. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process 10% of women of childbearing age above 5 ug/L is not current or verifiable; 2011-2012 NHANES shows 5% of females have mercury blood levels > 3.99 ug/L . Analysis by Buchannan et al. 2015 shows that 1.7% of women on child bearing age have blood mercury > 5.8 ug/L (RfD), while 5% > 3.6 ug/L.

Hope this helps.

Debbie

Cc: Wathen, John[Wathen.John@epa.gov]
To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]
From: Larimer, Lisa
Sent: Mon 3/14/2016 1:44:49 PM
Subject: Fw: Upcoming EWG report on mercury exposures for frequent fish consumers
EWG_Embargoed-MercuryHair_2015.pdf
US_Gives_Seafood_Eaters_Flawed_Advice_on_Mercury.pdf

I don't know you if you received this too, but if not, here you go! I haven't looked at it yet, but I hear our AA's office will be scheduling a meeting with these folks.

-Lisa

From: Sonya Lunder <sonya@ewg.org>
Sent: Friday, March 11, 2016 12:06 PM
To: Shapiro, Mike; Southerland, Elizabeth; Lape, Jeff; Larimer, Lisa
Subject: Upcoming EWG report on mercury exposures for frequent fish consumers

Environmental Working Group has long been concerned about the adequacy of EPA and FDA seafood advice for pregnant women. In 2014 we cautioned that women who follow the government recommendations and eat 2 to 3 seafood meals per week during pregnancy could ingest too much mercury.

Next week we are releasing a report that tested hair mercury levels for 254 women who eat 2 or more seafood meals per week. We found that 29% had hair mercury levels >= 1 part per million, roughly equivalent to the reference dose. We found that only 17% of estimated mercury ingestion was from the species presently named in the seafood advice, but that tuna (steaks, sushi, and canned albacore and light) made up 40% of the mercury in our study participants' diets.

We caution that FDA and EPA must expand mercury warnings to ensure that women who follow federal seafood advice achieve the intended benefits during pregnancy. I am attaching the upcoming hair mercury study as well a our 2014 analysis of federal seafood guidelines for your review.

I welcome the opportunity to brief your staff on the findings.

- Sonya Lunder

Sonya Lunder, MPH
Senior Analyst
Environmental Working Group
Washington DC 20009

Sonya@ewg.org
202/939-9129

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Larimer, Lisa
Sent: Tue 2/16/2016 7:16:32 PM
Subject: Have you heard anything from FDA on fish advice?

Hi Betsy,

We were wondering whether I should bug our workgroup compatriots at FDA or whether you wanted to. I've heard nothing Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Barash, Shari[Barash.Shari@epa.gov]
From: Larimer, Lisa
Sent: Wed 2/10/2016 6:39:56 PM
Subject: FW: Dr Oz article on mercury in fish
Dr. Oz Fish Article.pdf
Fish Advice Hg Trend Memo_FINAL_2016 02 01.pdf

FYI. Here's the Dr. Oz article I was telling you about.

From: Wathen, John
Sent: Tuesday, February 09, 2016 9:22 AM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: FW: Dr Oz article on mercury in fish

Kaycee-

Cutsie article on our favorite subject forwarded by FDA colleagues. While I'm sending, we also received **Ex. 5 - Deliberative Process**

~John

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Monday, February 08, 2016 5:41 PM
To: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Bernard, Susan <Susan.Bernard@fda.hhs.gov>
Subject: Dr Oz article on mercury in fish

Hot off the press (March 2016).

Ex. 5 - Deliberative Process

Regards,

Debbie

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Bigler, Jeff
Sent: Tue 4/14/2015 7:21:48 PM
Subject: RE: fish advice as of now

Thanks – I sent to Rebecca.

Decided it's best to just keep quiet with this meeting as it's apparently much easier to talk over folks when you're actually in the room.

From: Larimer, Lisa
Sent: Tuesday, April 14, 2015 3:16 PM
To: Bigler, Jeff
Subject: fish advice as of now

Date

Advice about Eating Fish: What Pregnant Women and Parents Should Know

Who Should Know

Ex. 5 - Deliberative Process

Key Advice

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Larimer, Lisa
Location: DCRoomWest1144C/OCHP
Importance: Normal
Subject: FW: update on FDA-EPA fish advice
Start Date/Time: Wed 7/29/2015 5:00:00 PM
End Date/Time: Wed 7/29/2015 6:00:00 PM
FISH_CHART_H_7.24.pdf
FISH_CHART_V_7.24.pdf
Fish Advice Qs and As-070915.docx
Fish advice-results of CHPAC recommendations.xlsx

Even though most of you cannot make the OW briefing this afternoon, it would be helpful to get your feedback re: (1) the brochure; (2) the draft Q&As; and (3) OW's response to the CHPAC recommendations.

Thanks

Michael

-----Original Appointment-----
From: Larimer, Lisa
Sent: Tuesday, July 28, 2015 4:03 PM
To: Larimer, Lisa; Firestone, Michael; Wathen, John
Cc: Berger, Martha; Reed, Khesha
Subject: update on FDA-EPA fish advice
When: Wednesday, July 29, 2015 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest1144C/OCHP

Please forward to anyone else who may be interested. And let me know if I have the wrong room. Thanks!

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: InsideEPA.com
Sent: Wed 1/18/2017 7:11:46 PM
Subject: Today's Must-Read News

January 18, 2017

Departing EPA Toxics Chief Sees OPPT, IRIS Link With TSCA Implementation

EPA's outgoing toxics chief Jim Jones sees the agency's growing Office of Pollution Prevention and Toxics (OPPT) working with the agency's influential Integrated Risk Information System (IRIS) program in the research office on chemicals in common as OPPT begins to implement its new Toxic Substances Control Act (TSCA) authorities to screen the safety of thousands of chemicals.

EPA, FDA Publish Final Fish Consumption Advice For Pregnant Women

EPA and the U.S. Food and Drug Administration (FDA) have published, after years of development, their final advice on fish consumption for women who are or may become pregnant, making several changes that appear to address concerns from public health advocates and children's health advisors regarding which fish should be limited or avoided.

Read all the latest EPA news, analysis and documents →

EDITORIAL CONTACT

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To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Firestone, Michael
Sent: Wed 8/5/2015 5:46:19 PM
Subject: RE: Briefing the Administrator on fish advice

Lisa

Thanks for asking – I'll check with OCHP management & get right back to you.

Michael P. Firestone, Ph.D.

Regulatory Support & Science Policy Division

Office of Children's Health Protection (MC 1107T)

Office of the Administrator

U.S. Environmental Protection Agency

Room 1130 EPA West Building

Washington, DC 20460

Office: 202-564-2199 (Monday thru Wednesday)

Cell: 202-213-4651 (Thursday)

FAX: 202-564-2733

From: Larimer, Lisa
Sent: Wednesday, August 05, 2015 1:45 PM
To: Firestone, Michael
Subject: Briefing the Administrator on fish advice

Hi Michael,

We're setting up a meeting with the Administrator on the FDA-EPA fish advice. Who, if anyone, from OCHP should be invited? (The guest list is getting quite large, so only key people please.)

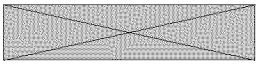
Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Rice, Nekia[Rice.Nekia@epa.gov]
From: Microsoft Outlook
Sent: Mon 9/21/2015 4:55:46 PM
Subject: Undeliverable: OCHP Staff Meetings
OCHP Staff Meetings



Your message to Rice.Nekia@epa.gov couldn't be delivered.

Rice.Nekia wasn't found at epa.gov

Reed.Khesha	**Office 365**	**Rice.Nekia**
Action Required		Recipient

Unknown TO address

How to Fix It

The address may be misspelled or may not exist. Try the following:

- **Retype the email address then resend the message.**
- **Clear the recipient nickname cache in Outlook or Outlook Web App by following the steps in this article: NDR Response Code 5.1.10 in Exchange Online and Office 365.**
- **Contact the recipient (by phone or instant messaging, for example) to check that the address is correct.**
- **The recipient may have set up mail forwarding to an incorrect address. Ask them to check that any forwarding they've set up is working correctly.**

If the problem continues, forward this message to your email admin.

Was this helpful? Send feedback.

More Info for Email Admins

This error occurs because the sender sent a message to someone whose mailbox is hosted by Office 365 but the email address is incorrect or doesn't exist. The error is reported by the recipient's email system, but most often it must be fixed by the person who sent it.

A common example of when this can happen is when the recipient changes their email address but the sender picks the person from their recipient nickname list in Outlook or Outlook Web App. The nickname cache doesn't yet know about the new e-mail address - it has stored the out-of-date email address information -- so when the message is sent the wrong address is used, even though the sender chose the right recipient.

Another example is if the recipient is an Office 365 user but a license is not assigned to the user. In the Office 365 Admin Center check that the user has a valid license assigned to it.

Sometimes it needs to be fixed by the recipient or the recipient's email admin, for example, when the recipient has created a mail forwarding rule to an incorrect address, or if there's a problem with their email address directory. If the sender is using the correct recipient address, and it's still not working, send a test message from another user mailbox to see if it's an issue unique to this sender. If you reproduce the problem sending from another user account, ask the recipient or the recipient's email admin to confirm that the recipient address exists, is correct, and is working. Suggest they check for misbehaving forwarding rules or possible email address directory issues (such as directory synchronization issues).

For more information, see NDR Response Code 5.1.10 in Exchange Online and Office 365.

Original Message Details

Created Date:	**9/21/2015 4:55:44 PM**
Sender Address:	**Reed.Khesha@epa.gov**
Recipient Address:	**Rice.Nekia@epa.gov**
Subject:	**OCHP Staff Meetings**

Error Details

Reported error:	***RESOLVER.ADR.RecipientNotFound; Recipient not found by SMTP address lookup***
DSN generated by:	**BL2PR09MB116.namprd09.prod.outlook.com**

Message Hops

HOP	TIME (UTC)	FROM	TO	WITH	RELAY TIME
1	9/21/2015 4:55:45 PM	BL2PR09MB0132.namprd09.prod.outlook.com	BL2PR09MB0132.namprd09.prod.outlook.com	mapi	1 sec
2	9/21/2015 4:55:46 PM	BL2PR09MB0132.namprd09.prod.outlook.com	BL2PR09MB116.namprd09.prod.outlook.com	Microsoft SMTP Server (TLS)	1 sec

Original Message Headers

```
Authentication-Results: epa.gov; dkim=none (message not signed)
 header.d=none;epa.gov; dmarc=none action=none header.from=epa.gov;
Received: from BL2PR09MB0132.namprd09.prod.outlook.com (10.255.233.142) by
 BL2PR09MB116.namprd09.prod.outlook.com (10.255.231.28) with Microsoft SMTP
 Server (TLS) id 15.1.274.16; Mon, 21 Sep 2015 16:55:46 +0000
Received: from BL2PR09MB0132.namprd09.prod.outlook.com ([10.255.233.142]) by
 BL2PR09MB0132.namprd09.prod.outlook.com ([10.255.233.142]) with mapi id
 15.01.0268.017; Mon, 21 Sep 2015 16:55:45 +0000
Content-Type: application/ms-tnef; name="winmail.dat"
Content-Transfer-Encoding: binary
```

From: "Etzel, Ruth" <Etzel.Ruth@epa.gov>
To: "Mehta, Suril" <Mehta.Suril@epa.gov>, "Schroeder, Kathleen"
<Schroeder.Kathleen@epa.gov>, "Firestone, Michael"
<Firestone.Michael@epa.gov>, "Belle, Kara" <Belle.Kara@epa.gov>,
"Basden,
Phyllis" <Basden.PhyllisC@epa.gov>, "Merse, Cynthia" <Merse.Cynthia@epa.gov>,
<Foos, Brenda" <Foos.Brenda@epa.gov>, "Beasley, Ally"
<Beasley.Ally@epa.gov>,
"Davis, Matthew" <Davis.Matthew@epa.gov>, "Dzubow, Rebecca"
<Dzubow.Rebecca@epa.gov>, "Switzer, LaVonne"
<Switzer.LaVonne@epa.gov>,
"Miller, Gregory" <Miller.Gregory@epa.gov>, "Berger, Martha"
<Berger.Martha@epa.gov>, "Nahar, Muna" <Nahar.Muna@epa.gov>,
"Khoury, Samar"
<Khoury.Samar@epa.gov>, "Reed, Khesha" <Reed.Khesha@epa.gov>,
"Brown, Margot"
<Brown.Margot@epa.gov>, "White, Sherri" <White.Sherri@epa.gov>,
"Kukla,
Alison" <Kukla.Alison@epa.gov>, "Rice, Nekia" <Rice.Nekia@epa.gov>,
"Anderson, BrianO" <Anderson.BrianO@epa.gov>
CC: "Nwana, Chinwude" <Nwana.Chinwude@epa.gov>, "Saulles, Ariel"
<Saulles.Ariel@epa.gov>, "Lee, Connie" <Lee.Connie@epa.gov>
Subject: OCHP Staff Meetings
Thread-Topic: OCHP Staff Meetings
Thread-Index: AdAp9VLivwoR6lYpQw6LjiDc/097ZwcFSliw
Sender: "Reed, Khesha" <Reed.Khesha@epa.gov>
X-MS-Exchange-MessageSentRepresentingType: 2
X-MS-Exchange-Calendar-Originator-Id: 54a18567-85f7-45c5-8acb-
494ff65fe054;/O=EXCHANGELABS/OU=EXCHANGE
ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=96A20535ABB54ED4ABF1E40D2AA916D9-ETZEL,
RUTH
Date: Mon, 21 Sep 2015 16:55:44 +0000
Message-ID:
<BL2PR09MB01322BC73CC8B156C69DDE0CFA460@BL2PR09MB0132.namprd09.prod.outlook.com>
Accept-Language: en-US
Content-Language: en-US
X-MS-Has-Attach:
X-MS-TNEF-Correlator:
<BL2PR09MB01322BC73CC8B156C69DDE0CFA460@BL2PR09MB0132.namprd09.prod.outlook.com>
MIME-Version: 1.0
X-Originating-IP: [134.67.6.11]
Return-Path: Reed.Khesha@epa.gov
X-Microsoft-Exchange-Diagnostics:
1;BL2PR09MB116;2:gqzfyKkMUuN/dqC8qTj907TfwklsIRhhcWzpAvfYk9IAI64nooeQDGFh+3f+y4u
X-Microsoft-Antispam: UriScan:;BCL:0;PCL:0;RULEID:;SRVR:BL2PR09MB116;
X-Microsoft-Exchange-Diagnostics:
1;BL2PR09MB116;20:8gzPI1R10PWTNNsmzZaUeAKPvfe7VBXJhh649uR6IzYihcrSkNp99PB6/XVomhI
X-Exchange-Antispam-Report-Test: UriScan:(108003899814671);
X-Exchange-Antispam-Report-CFA-Test:
BCL:0;PCL:0;RULEID:(601004)(8121501046)(520078)(3002001);SRVR:BL2PR09MB116;BCL:0
X-Forefront-Antispam-Report:
SFV:SKI;SFS:;DIR:INB;SFP:;SCL:-
1;SRVR:BL2PR09MB116;H:BL2PR09MB0132.namprd09.prod.outlook.com;FPR:;SPF:None;LANG:en;
X-Microsoft-Exchange-Diagnostics:
1;BL2PR09MB116;23:PX6b92XRIytmYqDT6ecC2s9pi0Vu65Xn4zbbi/HNjvr/Avz8GkU7q9fw8uDc9b
SpamDiagnosticOutput: 1:0
X-MS-Exchange-CrossTenant-OriginalArrivalTime: 21 Sep 2015 16:55:45.5277
(UTC)
X-MS-Exchange-CrossTenant-FromEntityHeader: Hosted

X-MS-Exchange-CrossTenant-Id: 88b378b3-6748-4867-acf9-76aacbeca6a7
X-MS-Exchange-Transport-CrossTenantHeadersStamped: BL2PR09MB116

From: Reed, Khesha
Location: Conference Room 1144C, WJC West, Conference C Ex. 6 - Personal Privacy
Ex. 6 - Personal Privacy
Importance: Normal
Subject: OCHP Staff Meetings
Start Date/Time: Mon 9/21/2015 6:30:00 PM
End Date/Time: Mon 9/21/2015 7:00:00 PM

OCHP Staff Meeting Agenda
September 21, 2015

1. Senior Staff Update
2. ISEE Conference Reports - Ally and Muna
3. Thank Yous
4. OCHP Updates

* Continuing to prepare for Children's Health Month. EPA internal communications office will be publicizing our Open House (10/5). We are working to finalize an agenda and location for the Task Force Principal's Meeting (10/14). The Administrator will be visiting a DC area Boys and Girls Club (date TBD). The CHM web page is live. We will continue to add regional events.
* The Administrator is being briefed on the FDA-EPA fish advice tomorrow.

5. General Information/Announcements

* Massive Open Online Course - October 13, 2015. This MOOC was developed by four eminent scientists who together authored the health chapter in the recent 5th Assessment report of the IPCC. They offer you a short crash-course into the topic of climate change, tailored to senior policy-makers and negotiators of climate agreements, particularly as an input into the climate conference COP21 in Paris in December this year. https://iversity.org/en/courses/ https://iversity.org/en/courses/climate-change-health-for-policy-makers
* BROWN BAG tomorrow (9/22) - to review policy posters. If you are working from home, you can call in and send comments to Khesha, Michelle and Ally.

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Reed, Khesha[Reed.Khesha@epa.gov]; Berger, Martha[Berger.Martha@epa.gov]; Foos, Brenda[Foos.Brenda@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Brown, Margot[Brown.Margot@epa.gov]; Davis, Kathy[Davis.Kathy@epa.gov]
From: Firestone, Michael
Sent: Wed 7/29/2015 1:28:57 PM
Subject: RE: update on FDA-EPA fish advice

PS - Here is a link to the CHPAC Dec. 2014 letter:
http://www2.epa.gov/sites/production/files/2015-01/documents/chpac_final_fish_advisory_recommendations.pdf

Michael P. Firestone, Ph.D.
Regulatory Support & Science Policy Division
Office of Children's Health Protection (MC 1107T)
Office of the Administrator
U.S. Environmental Protection Agency
Room 1130 EPA West Building
Washington, DC 20460
Office: 202-564-2199 (Monday thru Wednesday)
Cell: 202-213-4651 (Thursday)
FAX: 202-564-2733

-----Original Appointment-----
From: Firestone, Michael **On Behalf Of** Larimer, Lisa
Sent: Wednesday, July 29, 2015 9:27 AM
To: Khesha Reed (Reed.Khesha@epa.gov); Berger, Martha; Foos, Brenda; Brown, Margot; Davis, Kathy
Subject: FW: update on FDA-EPA fish advice
When: Wednesday, July 29, 2015 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest1144C/OCHP

Even though most of you cannot make the OW briefing this afternoon, it would be helpful to get your feedback re: (1) the brochure; (2) the draft Q&As; and (3) OW's response to the CHPAC recommendations.

Thanks

Michael

-----Original Appointment-----
From: Larimer, Lisa
Sent: Tuesday, July 28, 2015 4:03 PM
To: Larimer, Lisa; Firestone, Michael; Wathen, John
Cc: Berger, Martha; Reed, Khesha
Subject: update on FDA-EPA fish advice
When: Wednesday, July 29, 2015 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: DCRoomWest1144C/OCHP

Please forward to anyone else who may be interested. And let me know if I have the wrong room. Thanks!

<< File: FISH_CHART_H_7.24.pdf >> << File: FISH_CHART_V_7.24.pdf >> << File: Fish Advice Qs and As-070915.docx >> << File: Fish advice-results of CHPAC recommendations.xlsx >>

From: Berger, Martha
Location: DCRoomWest1144C/OCHP
Importance: Normal
Subject: FW: update on FDA-EPA fish advice
Start Date/Time: Wed 7/29/2015 5:00:00 PM
End Date/Time: Wed 7/29/2015 6:00:00 PM
FISH_CHART_H_7.24.pdf
FISH_CHART_V_7.24.pdf
Fish Advice Qs and As-070915.docx
Fish advice-results of CHPAC recommendations.xlsx

Come hear the latest on OW's fish advisories!

-----Original Appointment-----
From: Larimer, Lisa
Sent: Tuesday, July 28, 2015 4:03 PM
To: Firestone, Michael; Wathen, John
Cc: Berger, Martha; Reed, Khesha
Subject: update on FDA-EPA fish advice
When: Wednesday, July 29, 2015 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest1144C/OCHP

Please forward to anyone else who may be interested. And let me know if I have the wrong room. Thanks!

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: Berger, Martha
Sent: Tue 7/28/2015 3:02:29 PM
Subject: FW: Requesting an informal meeting on FDA-EPA updated fish advice
Fish advice-results of CHPAC recommendations.xlsx
Fish Advice Qs and As-070915.docx
FISH_CHART_H_7.18.pdf
FISH_CHART_V_7.18.pdf

What's the best way to handle this? Can it fit into Ruth's calendar or shall I just see if Michael can do it? Other options?

Martha Berger

Office of Children's Health Protection

US Environmental Protection Agency

202/564-2191

From: Larimer, Lisa
Sent: Tuesday, July 28, 2015 10:58 AM
To: Berger, Martha
Cc: Wathen, John
Subject: Requesting an informal meeting on FDA-EPA updated fish advice

Martha,

We in the Office of Science and Technology would love to update you on what the final version of the FDA-EPA fish advice is looking like and how CHPAC's recommendations were addressed. In an ideal world, we'd like to meet with Ruth Etzel and whichever staff are interested in this project before we brief our AA on Thursday afternoon. Whatever magic you can work on your end would be much appreciated.

Here are some relevant files in case people want to take a look before the meeting.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: fisher.jaccqulen@epa.gov[fisher.jaccqulen@epa.gov]
Cc: Reed, Khesha[Reed.Khesha@epa.gov]
From: Berger, Martha
Sent: Wed 12/3/2014 7:06:21 PM
Subject: Fwd: Fish Advisory Letter revised draft
PastedGraphic-1.tiff
ATT00001.htm
CHPAC Fish Advisory Letter Final Draft.docx
ATT00002.htm
Post Natal Mercury Exposure.xlsx
ATT00003.htm

Jackie, here is the latest draft of the fish letter.

Martha

Martha Berger
Office of Children's Health Protection
US Environmental Protection Agency
202/564-2191

Begin forwarded message:

From: "Forman, Joel" <joel.forman@mssm.edu>
Date: December 3, 2014 at 1:08:32 PM EST
To: Malloy Maureen <Maureen.Malloy@icfi.com>
Cc: "gov' 'barbara. morrissey@doh. wa." <barbara.morrissey@doh.wa.gov>, "Nancy Clark" <nclark@health.nyc.gov>, Buchanan MD MPH Susan <sbucha3@uic.edu>, "Lloyd Kolbe" <lkolbe@indiana.edu>, "edu' 'skuntz@montana." <skuntz@montana.edu>, Jeanne Leffers <jleffers@umassd.edu>, Joanne Perron <joanneperronmd@gmail.com>, "gov' 'berger. martha@epa." <Berger.Martha@epa.gov>, Sathyanarayana Sheela <sheela.sathyanarayana@seattlechildrens.org>, "Blaine, Susan" <Susan.Blaine@icfi.com>
Subject: Fish Advisory Letter revised draft

Here is the latest draft after our lunch time revisions.
Barb is sending citations.

I am also attaching my spreadsheet of references. The 1st column has the full reference for each one and can be used to create the list of publications that we reviewed and serve as the appendix for Charge 2. In addition, it should contain all the details needed for most of the citations in the letter.

Joel

--
Joel Forman, M.D.

Vice-Chair for Education and Residency Program Director
Department of Pediatrics
Icahn School of Medicine at Mount Sinai
1 Gustave L. Levy Place - Box 1512
New York, NY 10029-6574
(Tel) 212-241-6934
(Fax) 212-241-4309

On Dec 3, 2014, at 11:01 AM, Malloy, Maureen <Maureen.Malloy@icfi.com> wrote:

Dear Fish Advisory Workgroup,

Please find attached the Fish Advisory Letter with the 12/3 CHPAC discussion comments for your review. The purple comments are edits proposed after the CHPAC discussion.

Thanks,
Maureen

From: Malloy, Maureen
Sent: Tuesday, December 02, 2014 12:08 PM
To: Barbara Morrissey; Nancy Clark; Susan Buchanan; Joel Forman; Lloyd Kolbe; Sandra Kuntz; Jeanne Leffers; Joanne Perron
Cc: 'Berger, Martha'; 'sheela.sathyanarayana@seattlechildrens.org'; Blaine, Susan
Subject: RE: CHPAC Fish Advisory Workgroup Materials

Dear Fish Advisory Workgroup,

Please find attached Joel Foreman's spreadsheet of Post Natal Articles for your review.

Thanks,
Maureen

From: Malloy, Maureen
Sent: Monday, December 01, 2014 11:52 AM
To: Barbara Morrissey; Nancy Clark; Susan Buchanan; Joel Forman; Lloyd Kolbe; Sandra Kuntz; Jeanne Leffers; Joanne Perron
Cc: 'Berger, Martha'; 'sheela.sathyanarayana@seattlechildrens.org'; 'coopwood.theodore@epa.gov'; Blaine, Susan
Subject: CHPAC Fish Advisory Workgroup December Plenary Schedule

Dear Fish Advisory Workgroup,

This is a reminder of the Fish Advisory Workgroupschedule for the CHPAC December Plenary this Tuesday 12/2 and Wednesday 12/3. Please find the Workgroup schedule below.

- Fish Advisory Workgroup meeting on Tuesday, 12/2 from 8:30-11:30 am EDT.
- Fish Advisory Letter Presentation on Tuesday 12/2 from 1:45-2:45 pm EDT.
- Fish Advisory Letter Review on Wednesday 12/3 from 9:00-9:45 am EDT.

Please email Martha (Berger.Martha@epa.gov) or Susan (Susan.Blaine@icfi.com) if you have any questions and we look forward to seeing you.

Best,
Maureen

Maureen Malloy | ICF International
(o) 703-934-3741 | Maureen.Malloy@icfi.com

Maureen Malloy | ICF International
(o) 703-934-3741 | Maureen.Malloy@icfi.com

<CHPAC Fish Advisory Letter_Draft 120314 _mon am edits v2 CHPAC Discussion.docx>

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: Curtis, Mellasonda
Sent: Mon 9/21/2015 8:19:04 PM
Subject: RE: Materials for FDA-EPA Fish Advice briefing

The attachment is not added.

From: Reed, Khesha
Sent: Monday, September 21, 2015 4:17 PM
To: Curtis, Mellasonda
Subject: Fwd: Materials for FDA-EPA Fish Advice briefing

It looks like they added one more attachment for the FDA meeting tomorrow.

Sent from my iPhone

Begin forwarded message:

From: "Larimer, Lisa" <Larimer.Lisa@epa.gov>
To: "Wathen, John" <Wathen.John@epa.gov>, "Hisel-Mccoy, Sara" <Hisel-McCoy.Sara@epa.gov>, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>, "Burke, Thomas" <Burke.Thomas@epa.gov>, "Etzel, Ruth" <Etzel.Ruth@epa.gov>, "Coopwood, Theodore" <Coopwood.Theodore@epa.gov>, "Mitchell, Stacey" <Mitchell.Stacey@epa.gov>, "Schroer, Lee" <schroer.lee@epa.gov>, "Klasen, Matthew" <Klasen.Matthew@epa.gov>, "Ingram, Amir" <Ingram.Amir@epa.gov>
Cc: "Loop, Travis" <Loop.Travis@epa.gov>, "Lalley, Cara" <Lalley.Cara@epa.gov>, "Kavlock, Robert" <Kavlock.Robert@epa.gov>, "Hauchman, Fred" <hauchman.fred@epa.gov>, "Schoeny, Rita" <Schoeny.Rita@epa.gov>, "Reed, Khesha" <Reed.Khesha@epa.gov>, "Firestone, Michael" <Firestone.Michael@epa.gov>, "Penman, Crystal" <Penman.Crystal@epa.gov>, "Gentry, Nathan" <Gentry.Nathan@epa.gov>, "Foos, Brenda" <Foos.Brenda@epa.gov>, "Conerly, Octavia" <Conerly.Octavia@epa.gov>
Subject: Materials for FDA-EPA Fish Advice briefing

Ken

To: Hawkins, Denise[Hawkins.Denise@epa.gov]
Cc: Berger, Martha[Berger.Martha@epa.gov]; Reed, Khesha[Reed.Khesha@epa.gov]
From: Blaine, Susan
Sent: Thur 8/28/2014 6:24:06 PM
Subject: RE: CHPAC Meeting
CHPAC Agenda September 2014 - DRAFT 08-27-14.docx

Hi Denise,

We are excited to have you present to the CHPAC at the upcoming meeting. You are scheduled to present from 11:15 am – 12:00 pm on Wednesday, September 10. The working title is, "Fish Consumption Advisory: What Pregnant Women and Parents Should Know," and the meeting objective is "Receive an update on the EPA/FDA Fish Advisory Consumption in preparation for the newly charged workgroup." **As soon as possible**, please confirm the title and objective or provide better versions.

Presentation: Please submit your presentation to me (susan.blaine@icfi.com) by Thursday, September 4th (a draft version is great) so that we can provide some background information to our members. I can collect your final presentation on Monday, September 8th or when you arrive at the meeting.

Meeting Location: The CHPAC plenary will be held at the **National Archives Museum**, located at **700 Pennsylvania Ave NW, Washington, DC**.

- Tuesday, Sept. 9: We will meet in the Archivist Reception Room, which can be accessed via the museum entrance on Pennsylvania Avenue. Security will be aware of your attendance and escort you to the meeting space. If you have additional attendees joining you, please provide me with those names. Walk-in attendees are welcome, but the arrival process may be slower.

- Wednesday, Sept. 10: We will meet in the Jefferson room, which can be accessed via the Special Events entrance on Constitution Ave (see attached National Archives Map) and following the CHPAC directional signage. Please allow 15 minutes to access the National Archives building.

If you have any questions, please let me know.

Regards,

Susan

SUSAN BLAINE, CMP, CGMP | Senior Associate, Certified Meeting Planner | 703.225.2471 (o) | susan.blaine@icfi.com

From: Hawkins, Denise [mailto:Hawkins.Denise@epa.gov]
Sent: Thursday, August 28, 2014 1:58 PM
To: Blaine, Susan
Subject: CHPAC Meeting

Susan,

I will be speaking about the EPA-FDA fish advisory, in lieu of Jeff Bigler. Can you tell me when I'm on the agenda? Also, is there any information you need from me? (After today, I won't be back in the office until September 4.) Please let me know. Thanks,

Denise

Denise F. Hawkins, Chief

Fish, Shellfish, Beach and Outreach Branch

Office of Water/Office of Science and Technology

U.S. Environmental Protection Agency

Washington, D. C. 20460

202-566-1384

hawkins.denise@epa.gov

To: Michael Hatcher[MTH1@CDC.GOV]
Cc: Berger, Martha[Berger.Martha@epa.gov]; Reed, Khesha[Reed.Khesha@epa.gov]
From: Blaine, Susan
Sent: Wed 8/27/2014 6:56:57 PM
Subject: RE: Presentation Details - Children's Health Protection Advisory Committee (CHPAC)
CHPAC Agenda September 2014 - DRAFT 08-22-14_For Speakers.docx
Parking and Metro Map.pdf
National Archives Map-Special Events.pdf

Dr. Hatcher,

Due to some changes at the National Archives we will now be meeting in the Archivist's Reception Room on September 9th. This room can be accessed via the Pennsylvania Avenue side of the museum and you will be required to go through security and provide your driver's license. All members of the public are still welcome and encouraged to attend, but we are attempting to provide a list to the museum's security with all possible attendees.

Do you anticipate any colleagues traveling with you to this meeting? If so, please provide their name(s) and we will add them to the list. Individuals not on the list are welcome to attend, but the check-in process may be a little longer for them.

Thank you and we look forward to seeing you.

SUSAN BLAINE, CMP, CGMP | Senior Associate, Certified Meeting Planner | 703.225.2471 (o) | susan.blaine@icfi.com

From: Blaine, Susan
Sent: Tuesday, August 26, 2014 1:53 PM
To: Michael Hatcher
Cc: Berger, Martha (Berger.Martha@epa.gov); Reed, Khesha
Subject: RE: Presentation Details - Children's Health Protection Advisory Committee (CHPAC)

Dr. Hatcher,

Per my voice message, we are working to finalize the agenda for the CHPAC meeting in the next

day or two. In order to best inform the attendees on what to expect from your presentation, could you please provide a working title and objective? We currently have your working title as, "Prenatal Exposures (ATSDR and PEHSU Activities)" and the objective as, "Learn about recent ATSDR activities, including pediatric environmental health."

Thank you for your contributions,

Susan

SUSAN BLAINE, CMP, CGMP | Senior Associate, Certified Meeting Planner | 703.225.2471 (o) | susan.blaine@icfi.com

From: Blaine, Susan
Sent: Friday, August 22, 2014 2:48 PM
To: Blaine, Susan
Cc: Berger, Martha (Berger.Martha@epa.gov); Reed, Khesha
Subject: Presentation Details - Children's Health Protection Advisory Committee (CHPAC)

Greetings:

Thank you for agreeing to participate as a speaker at the September meeting of EPA's Children's Health Protection Advisory Committee (CHPAC). Please see attached for the agenda. At this time we are looking for a few items from you and ask that you reply at your earliest convenience.

Presentation Title: The agenda lists a working title. Please confirm this title or provide one that best suits your presentation

Objective: Please provide a few short words to describe the objective of your presentation.

Presentation: Please submit your presentation to me (susan.blaine@icfi.com) by Thursday, September 4th (a draft version is great) so that we can provide some background information to our members. I can collect your final presentation on Monday, September 8th or when you arrive

at the meeting.

Meeting Location: The CHPAC plenary will be held at the **National Archives Museum**, located at **700 Pennsylvania Ave NW, Washington, DC**.

•□□□□□□□ Tuesday, Sept. 9: We will meet in the Archivist Reception Room, which can be accessed via the museum entrance on Pennsylvania Avenue. Security will be aware of your attendance and escort you to the meeting space. If you have additional attendees joining you, please provide me with those names. Walk-in attendees are welcome, but the arrival process may be slower.

•□□□□□□□ Wednesday, Sept. 10: We will meet in the Jefferson room, which can be accessed via the Special Events entrance on Constitution Ave (see attached National Archives Map) and following the CHPAC directional signage. Please allow 15 minutes to access the National Archives building.

If you have any questions, please let me know.

Regards,

Susan

SUSAN BLAINE, CMP, CGMP | Senior Associate, Certified Meeting Planner | 703.225.2471 (o) | susan.blaine@icfi.com | icfi.com

ICF INTERNATIONAL | 9300 Lee Highway, Fairfax, VA 22031 | 703.934.3740 (f)

Connect with us on social media.

U.S. Environmental Protection Agency
CHILDREN'S HEALTH PROTECTION ADVISORY COMMITTEE
National Archives Museum
700 Pennsylvania Avenue, NW, Washington, DC 20408

Tuesday, September 9th: Use entrance on Pennsylvania Avenue
Wednesday, September 10th: Use entrance on Constitution Avenue near 7th Street

Ex. 6 - Personal Privacy

September 9-10, 2014

Meeting Objectives

- Receive information on selected major initiatives in child health research at the National Institutes of Health, including the National Children's Study and the Human Placenta Project.
- Discuss EPA's responses to CHPAC letters, including Prenatal Exposures and Social Determinants of Health.
- Learn about recent ATSDR activities, including pediatric environmental health.
- Learn about the Interagency Report on Climate and Health.
- Review the EPA proposal for Lead NAAQS regulation.
- Receive information on the Clean Power Plan Proposed Rule.
- Receive an update on EPA's Office of Children's Health Protection activities.
- Review the newly formed workgroups and the charges to the CHPAC.
- Discuss the Administrator Priorities letter.
- Learn about the Clean Power Plan Proposed Rule and opportunities for comment.
- Receive updates on the EPA Research Roadmap and the children's health focus in the ORD Strategic Plan.
- Receive an update on the EPA/FDA Fish Consumption Advisory in preparation for the newly charged workgroup.
- Learn about EPA's new environmental justice screening tool.

Agenda
Tuesday, September 9, 2014

8:30 – 9:00 **COFFEE**

9:00 – 9:15 **Welcome and Review of Meeting Agenda**

Sheela Sathyanarayana, CHPAC Chair

9:15 – 10:00 **Children's Health Research at NIH**

Alan Guttmacher, Director
NIH, National Institute of Child Health and Human Development (NICHD)

Group Discussion

10:00 – 10:15 **BREAK**

10:15 – 10:30 **Discussion of Prenatal Exposures Letter**

CHPAC Letter and EPA Response – Susan Buchanan, Martha Sandy, CHPAC

Group Discussion

10:30 – 11:15 **Prenatal Exposures** (continued; ATSDR and PEHSU Activities)

Michael Hatcher
CDC, Agency for Toxic Substances and Disease Registry (ATSDR)

Group Discussion

11:15 – 12:00 **Interagency Report on Climate and Health**

Allison Crimmins
EPA, Office of Air and Radiation (OAR)

Group Discussion

12:00 – 1:00 **LUNCH – on your own; a list of nearby restaurants is available.**

1:00 – 2:30 **Lead NAAQS**

Gary Ginsberg – Former CHPAC Member; Connecticut Dept. of Public Health
Ellen Kirrane – EPA, Office of Research and Development (ORD)
Deirdre Murphy – EPA, Office of Air Quality Planning and Standards (OAQPS)

2:30 – 3:00 **Public Comment**

3:00 **ADJOURN**

Wednesday, September 10, 2014

8:00 – 8:30	**COFFEE**
8:30 – 9:15	**Office of Children's Health Protection Update** **Formation of New Workgroups** Khesha Reed, Acting Director EPA Office of Children's Health Protection Group Discussion
9:15 – 9:30	**Administrator Priorities Letter: Work Group Findings and Discussion** Jennifer Lowry, Work Group Chair Group Discussion
9:30 – 10:15	**Carbon Pollution: The Clean Power Plan** EPA, Office of Air and Radiation (OAR) Group Discussion
10:15 – 11:00	**EPA Research Roadmap and Translation** Sheela Sathyanarayana, CHPAC Chair Elaine Hubal, EPA, National Center for Computational Toxicology (NCCT) Group Discussion
11:00 – 11:15	**BREAK**
11:15 – 12:00	**Fish Consumption Advisory: What Pregnant Women and Parents Should Know** Jeff Bigler, National Program Manager EPA, Office of Water (OW) Group Discussion
12:00 – 12:20	**Discussion of Social Determinants of Health Letter** CHPAC Letter and EPA Response – Jeanne Leffers, CHPAC Group Discussion
12:20 – 1:05	**EJSCREEN: EPA's New Environmental Justice Screening Tool** Matthew Tejada, Director EPA, Office of Environmental Justice (OEJ) Group Discussion
1:05 – 1:15	**Wrap Up**
1:15	**ADJOURN**

From: Hisel-Mccoy, Sara
Location: DCRoomWest1144C/OCHP
Importance: Normal
Subject: EPA-FDA Fish Advice
Start Date/Time: Thur 9/29/2016 8:00:00 PM
End Date/Time: Thur 9/29/2016 8:50:00 PM

POCs: Evelyn McRae (202.566.1018) or Mellasonda Curtis (202.566.9971) for schedule questions; Lisa Larimer, 202.566.1017 for meeting information.

Mellasonda Curtis will open the conference line; meeting is in Conference Room 1144C WJCW, Office of Children's Health Protection.

Conference Number: Ex. 6 - Personal Privacy

Conference Access C

From: Anderson, Denise
Location: DCRoomARN3530CFTB/DC-Ariel-Rios-AO
Importance: Normal
Subject: FDA-EPA Fish Advice
Start Date/Time: Tue 9/22/2015 3:00:00 PM
End Date/Time: Tue 9/22/2015 3:45:00 PM
FISH_CHART_V_9.2.pdf
FDA-EPA Fish Advice briefing for DA.PPTX
FISH_CHART_H_9.2.pdf

Point of Contact for the Meeting: Lisa Larimer 566-1017
SCt: Denise Anderson, 564-1782

Call In # Ex. 6 - Personal Privacy

Purpose:	Share the final joint FDA-EPA fish advice with EPA senior leadership. HHS senior leadership is receiving a comparable briefing. The workgroup's goal is to announce the advice in September/October 2015, contingent upon timing of review by HHS and OMB.
Background:	An FDA-EPA workgroup has developed an update to the March 2004 fish advisory on mercury in fish and shellfish. The advice recommends consumption frequencies for the target audience of pregnant and breastfeeding women, women who could become pregnant, and children.
Last possible date for the meeting:	After 9/9/15 and before 9/25/15
EPA Staff (Required):	OW: Lisa Larimer, John Wathen, Sara Hisel-McCoy, Elizabeth Southerland, Ken Kopocis, Ellen Gilinsky ORD: Thomas Burke OA: Ruth Etzel, Theodore Coopwood OGC: Stacey Mitchell, Lee Schroer
EPA Staff (Optional):	OW: Travis Loop, Cara Lalley ORD: Robert Kavlock, Fred Hauchman, Rita Schoeny OA: Khesha Reed, Michael Firestone

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: Southerland, Elizabeth
Sent: Mon 8/18/2014 9:31:13 PM
Subject: Re: Children's Health Protection Advisory Committee

I forwarded your email on to staff and will get back to you tomorrow.

Sent from my iPhone

On Aug 18, 2014, at 5:27 PM, "Reed, Khesha" <Reed.Khesha@epa.gov> wrote:

Betsey,

I heard back from FDA. They are fine with CHPAC providing advice on the Fish Advisory. They even approved the charge!

Ex. 5 - Deliberative Process

We are behind schedule in finalizing the agenda, so a quick response would be greatly appreciated.

Please give me a call if you have questions. Thanks for your help.

Khesha Reed

Acting Director

Office of Children's Health Protection

Environmental Protection Agency

1200 Pennsylvania Ave, NW
Mailcode 1107T
Washington, DC 20460

(202) 566-0594

From: Reed, Khesha
Sent: Thursday, August 14, 2014 7:03 PM
To: Southerland, Elizabeth
Subject: Re: Children's Health Protection Advisory Committee

I don't understand either. It seems that they are hung up on the fact that we didn't specifically say that the CHPAC would review years ago and it was not specifically outlined in the FR notice.

Hopefully I'll hear back from her tomorrow. I really need to finalize the agenda.

I'll keep you informed.

Sent from my iPhone

On Aug 14, 2014, at 3:35 PM, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov> wrote:

Ex. 5 - Deliberative Process

From: Reed, Khesha
Sent: Thursday, August 14, 2014 2:23 PM
To: Southerland, Elizabeth
Subject: FW: Children's Health Protection Advisory Committee

Betsey,

I've been a little swamped lately and just realized that I hadn't kept you in the loop regarding my discussions with FDA. Sharon and I have talked a few times. The bottom line is - we haven't reached a solution yet. The chain of emails below can fill you in on where we are now.

Feel free to give me a call if you need more info or want to discuss.

Thanks,

Khesha Reed

Acting Director

Office of Children's Health Protection

Environmental Protection Agency
1200 Pennsylvania Ave, NW
Mailcode 1107T
Washington, DC 20460

(202) 566-0594

From: Reed, Khesha
Sent: Tuesday, August 12, 2014 5:19 PM
To: 'Natanblut, Sharon'
Subject: RE: Children's Health Protection Advisory Committee

Sharon,

I appreciate you getting back to me quickly and again apologize for missing your original response. I have answered your questions (below in green). Please feel free to give me a call if you have additional questions or need clarification.

Thanks,

Khesha Reed

Acting Director

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From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, August 11, 2014 3:32 PM
To: Reed, Khesha
Subject: RE: Children's Health Protection Advisory Committee

If you could provide the first two items right away, and follow-up with the others, we'd really appreciate it. I did a quick check and didn't see the FR notice.

Thanks.

Sharon

From: Natanblut, Sharon
Sent: Monday, August 11, 2014 3:28 PM
To: 'Reed, Khesha'
Subject: RE: Children's Health Protection Advisory Committee

Hi Khesha,

We do have several requests for information with regard to the September meeting and would greatly appreciate if you could provide the following:

1. the FR notice issued about the September meeting (as well as any other info made public about this meeting) – Here's the link to the FR notice http://www.gpo.gov/fdsys/pkg/FR-2014-08-11/html/2014-18931.htm. This notice and a meeting announcement on our website http://www2.epa.gov/children/childrens-health-protection-advisory-committee-chpac are the only sources of public information about the meeting.

2. the list of questions you are planning to ask the committee to consider. This is a draft charge based on the FRN. We will work with you and the EPA Office of Water to finalize.

Ex. 5 - Deliberative Process

3. the agenda (or are you still developing it) – is the entire meeting devoted to the seafood advice or is it just one topic – We are still developing the agenda. It is not yet available to the public. We would like to add one session on the fish advisory topic.

We would like someone from FDA (and/or EPA) to give background on the draft updated advice. In addition it would be helpful if the presentation included a review of the studies considered related to questions 1 and 2 above.

Also, we had some other questions:

Ex. 5 - Deliberative Process

We realize the meeting is less than a month away and so we want to be able to get back to you as soon as possible. If you would find it easier for us to have a call to discuss the questions above, we would be pleased to arrange that.

Many thanks.

Sharon Natanblut

Director, Strategic Communications and Public Engagement

FDA Foods and Veterinary Medicine Directorate

From: Reed, Khesha [mailto:Reed.Khesha@epa.gov]
Sent: Wednesday, August 06, 2014 5:43 PM
To: Natanblut, Sharon
Subject: Children's Health Protection Advisory Committee

Sharon,

After discussing the outreach plan with EPA senior managers, we would like to engage the Children's Health Protection Advisory Committee (CHPAC) on the draft advice "Fish: What Pregnant Women and Parents Should Know". The CHPAC is a body of external researchers, academicians, health care providers, environmentalists, state and tribal government employees, and members of the public who advise EPA on regulations, research, and communications related to children's health. Members serve voluntarily and the CHPAC meets about two or three times per year to provide specific recommendations to the EPA administrator.

We believe that the third supplemental question posed in the FR noticed is ideally suited for the CHPAC's mission and expertise.

(3) Information upon which to base advice on young children's fish consumption. There have been a number of studies that have examined the effects of both postnatal exposure to mercury as well as postnatal fish consumption by young children, but this research has not been as extensive as the research on prenatal exposures and maternal fish consumption.

We believe the CHPAC would provide valuable feedback and propose directing the CHPAC to respond to this charge during the current comment period. The next CHPAC meeting is scheduled for September 9th and 10th. We could form a workgroup that can begin to draft a response at this meeting. Alternatively, the CHPAC could join the FDA Advisory Committee on Risk Communication to jointly provide advice to the EPA Administrator and FDA Commissioner on both risk communications and fish consumption.

We are currently drafting the agenda for the September meeting and welcome your feedback as we determine if it should include the fish advisory now or table the topic for a joint meeting.

Feel free to contact me if you have questions or concerns.

Thank you,

Khesha Reed

Acting Director

Office of Children's Health Protection

(202) 566-0594

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: Natanblut, Sharon
Sent: Mon 8/18/2014 8:09:51 PM
Subject: RE: Children's Health Protection Advisory Committee

Thank you Khesha. I'll keep at it.

From: Reed, Khesha [mailto:Reed.Khesha@epa.gov]
Sent: Monday, August 18, 2014 4:04 PM
To: Natanblut, Sharon
Subject: RE: Children's Health Protection Advisory Committee

I understand. I am free for the rest of the afternoon. Look forward to hearing from you.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, August 18, 2014 3:58 PM
To: Reed, Khesha
Subject: RE: Children's Health Protection Advisory Committee

Khesha, I'm so sorry – I've been trying all day. I will do so again.

Sharon

From: Reed, Khesha [mailto:Reed.Khesha@epa.gov]
Sent: Monday, August 18, 2014 11:09 AM
To: Natanblut, Sharon
Subject: RE: Children's Health Protection Advisory Committee

I have a CHPAC Steering Committee Meeting at noon. Can we talk before then?

Khesha Reed

Acting Director

Office of Children's Health Protection

Environmental Protection Agency
1200 Pennsylvania Ave, NW
Mailcode 1107T
Washington, DC 20460

(202) 566-0594

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Friday, August 15, 2014 6:36 PM
To: Reed, Khesha
Subject: RE: Children's Health Protection Advisory Committee

Khesha,

My hope is that we can talk Monday – early in the day. I totally understand your need to finalize the agenda.

Have a good weekend. Please email me on Monday if you don't hear from me when you need to.

Sharon

From: Reed, Khesha [mailto:Reed.Khesha@epa.gov]
Sent: Friday, August 15, 2014 4:30 PM
To: Natanblut, Sharon
Subject: RE: Children's Health Protection Advisory Committee

Sharon,

When do you think you might be able to give me feedback? We need to finalize the agenda as soon as possible.

I am working from home today. You can reach me on my cell phone if you have questions.

Thanks,

Khesha

202-407-0507

From: Reed, Khesha
Sent: Tuesday, August 12, 2014 5:19 PM
To: Natanblut, Sharon
Subject: RE: Children's Health Protection Advisory Committee

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(202) 566-0594

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To: Reed, Khesha
Subject: RE: Children's Health Protection Advisory Committee

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Subject: RE: Children's Health Protection Advisory Committee

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Ex. 5 - Deliberative Process

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Also, we had some other questions:

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From: Southerland, Elizabeth
Sent: Thur 8/14/2014 7:35:33 PM
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Thanks Khesha.

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Sharon,

So sorry. I was having computer issues last week and just noticed that I missed your email from 8/7/14. I'll work on these questions and get back to you ASAP.

Khesha Reed

Acting Director

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Office of Children's Health Protection

(202) 566-0594

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: Natanblut, Sharon
Sent: Mon 8/11/2014 7:32:11 PM
Subject: RE: Children's Health Protection Advisory Committee

If you could provide the first two items right away, and follow-up with the others, we'd really appreciate it. I did a quick check and didn't see the FR notice.

Thanks.

Sharon

From: Natanblut, Sharon
Sent: Monday, August 11, 2014 3:28 PM
To: 'Reed, Khesha'
Subject: RE: Children's Health Protection Advisory Committee

Hi Khesha,

We do have several requests for information with regard to the September meeting and would greatly appreciate if you could provide the following:

1. the FR notice issued about the September meeting (as well as any other info made public about this meeting)

2. the list of questions you are planning to ask the committee to consider.

3. the agenda (or are you still developing it) – is the entire meeting devoted to the seafood advice or is it just one topic

Also, we had some other questions:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

We realize the meeting is less than a month away and so we want to be able to get back to you as soon as possible. If you would find it easier for us to have a call to discuss the questions above, we would be pleased to arrange that.

Many thanks.

Sharon Natanblut

Director, Strategic Communications and Public Engagement

FDA Foods and Veterinary Medicine Directorate

From: Reed, Khesha [mailto:Reed.Khesha@epa.gov]
Sent: Wednesday, August 06, 2014 5:43 PM
To: Natanblut, Sharon
Subject: Children's Health Protection Advisory Committee

Sharon,

After discussing the outreach plan with EPA senior managers, we would like to engage the Children's Health Protection Advisory Committee (CHPAC) on the draft advice "Fish: What Pregnant Women and Parents Should Know". The CHPAC is a body of external researchers, academicians, health care providers, environmentalists, state and tribal government employees, and members of the public who advise EPA on regulations, research, and communications related to children's health. Members serve voluntarily and the CHPAC meets about two or three times per year to provide specific recommendations to the EPA administrator.

We believe that the third supplemental question posed in the FR noticed is ideally suited for the CHPAC's mission and expertise.

(3) Information upon which to base advice on young children's fish consumption. There have been a number of studies that have examined the effects of both postnatal

exposure to mercury as well as postnatal fish consumption by young children, but this research has not been as extensive as the research on prenatal exposures and maternal fish consumption.

We believe the CHPAC would provide valuable feedback and propose directing the CHPAC to respond to this charge during the current comment period. The next CHPAC meeting is scheduled for September 9th and 10th. We could form a workgroup that can begin to draft a response at this meeting. Alternatively, the CHPAC could join the FDA Advisory Committee on Risk Communication to jointly provide advice to the EPA Administrator and FDA Commissioner on both risk communications and fish consumption.

We are currently drafting the agenda for the September meeting and welcome your feedback as we determine if it should include the fish advisory now or table the topic for a joint meeting.

Feel free to contact me if you have questions or concerns.

Thank you,

Khesha Reed

Acting Director

Office of Children's Health Protection

(202) 566-0594

From: Smith, Kelley
Location: Ex. 6 - Personal Privacy
Importance: Normal
Subject: FDA-EPA Fish Advice Check in with Dr. Etzel
Start Date/Time: Tue 10/13/2015 1:15:00 PM
End Date/Time: Tue 10/13/2015 1:30:00 PM

Quick check in prior to FDA-EPA Fish Advice meeting with Stan Meiburg.

To: Reed, Khesha[Reed.Khesha@epa.gov]; Berger, Martha[Berger.Martha@epa.gov]
Cc: Deener, Kathleen[Deener.Kathleen@epa.gov]; Gwinn, Maureen[gwinn.maureen@epa.gov]
From: Smith, Kelley
Sent: Tue 11/10/2015 9:09:48 PM
Subject: CHPAC Event Memo 11 12 2015 v3.docx
CHPAC Event Memo 11 12 2015 v3.docx

Khesha and Martha,

Thank you again for your feedback on the last round of the event memo. I have added in summaries of the letters you suggested and written out some possible questions for Dr. Burke on the due outs section at the end. Can you take a quick skim and let me know if you have any final comments?

I am looping Maureen for her advice as well since she frequently works with Dr. Kavlock on requests to advisory groups.

If possible I would like to finalize this memo by 4pm at the latest so we can get it into his briefing book for Thursday.

Best,

KS

THE ENVIRONMENTAL PROTECTION AGENCY
Washington

November 10, 2015

EVENT MEMO FOR DR. THOMAS BURKE

FROM: KHEESHA REED, MEREDITH BERGER, AND KELLEY SMITH

SUBJECT: CHILDREN'S HEALTH PROTECTION ADVISORY COMMITTEE YEARLY MEETING

Background

The Children's Health Protection Advisory Committee (CHPAC) is a body of external researchers, academicians, health care providers, environmentalists, state and tribal government employees, and members of the public who advise EPA on regulations, research, and communications related to children's health. Members serve voluntarily and the CHPAC meets about two or three times per year to provide specific recommendations to the EPA Administrator. The Office of Children's Health Protection (OCHP) serves as the main point of contact for the CHPAC committee and Martha Berger from OCHP is the Designated Federal Official for the CHPAC.

The legal authority for CHPAC is the Federal Advisory Committee Act (FACA), 5 USC App 2. CHPAC acts in the public interest and supports EPA in performing its duties and responsibilities under Executive Order 13045 of April 21, 1997 (62 Fed Reg 19885; April 23, 1997). CHPAC provides advice on topics such as air and water pollution regulations, chemical safety programs, risk assessment policies, and research, which reflect the wide ranging environmental issues which affect the health of children. While most attention is paid to domestic issues, CHPAC sometimes addresses global issues such as climate change.

Two years ago the Administrator challenged the CHPAC members to give her a small number of priorities to focus on in the end of the Obama Administration. They deliberated for six months and then responded with the following priorities (see briefing materials for full letter):

1. CHPAC recommends that you convene the President's Task Force on Environmental Health and Safety Risks to Children at the cabinet level in 2014 and at least annually thereafter with the following actionable items:

    a. Improve access and funding for children's environmental preventive healthcare services

    b. Engage relevant accrediting and certifying organizations for medical and nursing schools to develop and implement education standards and curricula for children's environmental health

c. Integrate environmental health assessments into healthcare information management systems

2. CHPAC recommends that you increase the capacity of EPA to more effectively protect children's health. You can accomplish this recommendation with the following actions:

a. Increase the number of Office of Children's Health Children's Health Protection staff that have both children's environmental health expertise and designated responsibility for children's health initiatives and policies.

b. Require OCHP review, guidance, and concurrence with the application of safety factors protective of prenatal, infant and child populations in all Agency rules and regulations, with a specific focus on pesticide registration/re-registration eligibility decision documents and other pesticide risk assessments.

c. Increase the number of managers and staff with children's environmental health expertise within all EPA programs, regional offices and its partners responsible for protecting prenatal, infant, and child populations from environmental health risks.

3. CHPAC recommends that that you advocate throughout EPA and with other federal agencies to increase the capacity of PEHSUs to provide science-based environmental health education and technical assistance to health care professionals, health departments, schools and community organizations, especially those that serve vulnerable communities.

More recently the CHPAC membership has written the Administrator on the FDA/EPA Fish Advisory and CH Priorities (2014), Ozone National Ambient Air Quality Standards (NAAQS 2014), and NAAQS for Lead (2015). In summary these letters advised:

- That EPA consider the following in regards to the **FDA/EPA Fish Advisory**:
    - Include Orange Roughly and Marlin in do not eat category because of high mercury and low omega-3 content.
    - Raised concern that consumers may assume other fish species high in mercury that are not named in the advisory are safe for pregnant women to eat
    - Recommended EPA consider tiered consumption guide similar to what many states use (like green, yellow, red lights)
    - Provide specific guidance of various species of fresh, frozen, and packaged tuna in the advisor instead of the Q&A since tuna comprises a significant portion of the fish that Americans consume
    - EPA should include young children in the advisor as a public health protective measure because of uncertainties regarding the risks posed by high mercury fish consumption
    - Construct fish consumption advise to encourage fish consumption by emphasizing benefits of fish, recommend lowest mercury fish for children, and

ensure that low income, low literacy, and non-English speaking communities can understand the messages.
    - Conduct comprehensive literature review of mercury risk and nutritional benefits of fish consumption and support research that strengthens evidence and fills data gaps associated with the risks and benefits of fish consumption.
    - EPA should collaborate with FDA to ensure fish advice is consistent and review current state and local advisories for guidance and messaging consistency
    - Improve internet navigation from federal advice pages to state advisory webpages
    - Test messaging and graphics with focus groups before finalizing the advice
    - Lastly, provide funds to state, local health departments, and tribes to develop and disseminate advisories that are better tailored to their local communities.

- That the **Ozone NAAQS** be lowered to 60ppb in order to be protective of childrens health. This was a reaffirmation of the CHPAC recommendation in 2007 that the Ozone NAAQS be set at 60ppb or less in order to adequately protect children's health

- That the current **Lead NAAQS** are not adequately protective to children's health and propose that the new standard be lowered to 0.02 µg/m3, that the standard should be based on a shorter monitoring period of one month to capture transient sources, and that EPA should use a more robust network to adequately estimate children's lead exposures from transient and other sources.

Ex. 5 - Deliberative Process

Event Background

YOU are scheduled to speak to the 25 CHPAC members from 1:15 – 2:15 PM on November 12 at the National Archives. We have allotted 20-30 min for your remarks and 15-30 min for Q&A from the members.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: Foos, Brenda
Sent: Thur 9/10/2015 6:22:32 PM
Subject: RE: FDA-EPA Fish Advice

This just showed up today and we need to be sure to cover it at the huddle on Monday. Thanks -

Brenda

****

Brenda Foos
Director, Regulatory Support and Science Policy Division
US EPA Office of Children's Health Protection
202-564-2707

-----Original Appointment-----
From: Firestone, Michael **On Behalf Of** Meiburg, Stan
Sent: Thursday, September 10, 2015 10:23 AM
To: Foos, Brenda
Subject: Fw: FDA-EPA Fish Advice
When: Thursday, September 17, 2015 5:00 PM-5:45 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomARN3530CFTB/DC-Ariel-Rios-AO

Michael P. Firestone, Ph.D.,
Regulatory Support & Science Policy Division
Office of Children's Health Protection (MC 1107T)
Office of the Administrator
U.S. Environmental Protection Agency
Room 1130 EPA West Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Office: 202-564-2199
Cell: 202-213-4651
FAX: 202-564-2733

From: Anderson, Denise on behalf of Meiburg, Stan
Sent: Thursday, September 10, 2015 10:21 AM
To: Larimer, Lisa; Wathen, John; Hisel-Mccoy, Sara; Southerland, Elizabeth; Kopocis, Ken; Gilinsky, Ellen; Burke, Thomas; Etzel, Ruth; Coopwood, Theodore; Mitchell, Stacey; Schroer, Lee; Klasen, Matthew; Ingram, Amir
Cc: Loop, Travis; Lalley, Cara; Kavlock, Robert; Hauchman, Fred; Schoeny, Rita; Reed, Khesha; Firestone, Michael; Penman, Crystal; Gentry, Nathan
Subject: FDA-EPA Fish Advice
When: Thursday, September 17, 2015 5:00 PM-5:45 PM.
Where: DCRoomARN3530CFTB/DC-Ariel-Rios-AO

Point of Contact for the Meeting: Lisa Larimer 566-1017
SCt: Denise Anderson, 564-1782

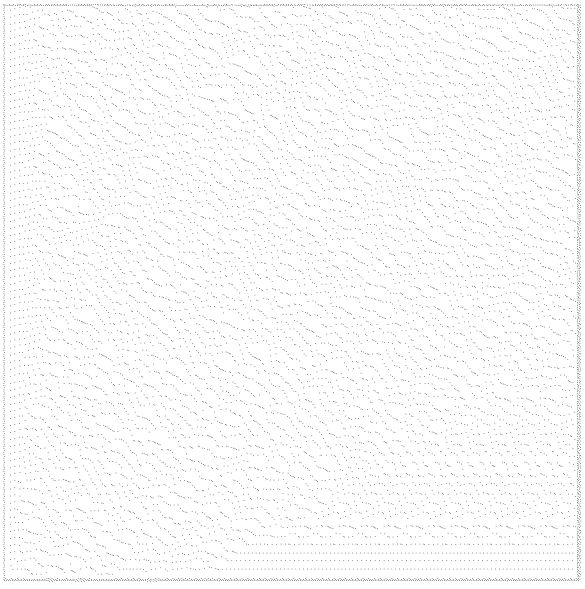
hare the final joint FDA-EPA fish advice with EPA senior leadership. HHS senior leadership is receiving a comparable briefing. The workgroup's goal is to announce the advice in September/October 2015, contingent upon timing of review by HHS and OMB.

An FDA-EPA workgroup has developed an update to the March 2004 fish advisory on mercury in fish and shellfish. The advice recommends consumption frequencies for the target audience of pregnant and breastfeeding women, women who could become pregnant, and children.

Last possible date for the meeting: After 9/9/15 and before 9/25/15

uired): OW: Lisa Larimer, John Wathen, Sara Hisel-McCoy, Elizabeth Southerland, Ken Kopocis, Ellen Gilinsky
mas Burke
Etzel, Theodore Coopwood
ey Mitchell, Lee Schroer

ional): OW: Travis Loop, Cara Lalley
ert Kavlock, Fred Hauchman, Rita Schoeny
ha Reed, Michael Firestone



<< File: Briefing Memo FDA-EPA fish advice.docx >>

To: Reed, Khesha[Reed.Khesha@epa.gov]; Foos, Brenda[Foos.Brenda@epa.gov]
From: Mehta, Suril
Sent: Mon 9/21/2015 7:22:02 PM
Subject: Re: OCHP Staff Meetings

No worries!

Suril Mehta

Health Scientist

Regulatory Support and Science Policy Division

Office of Children's Health Protection | US EPA

Ph: 202-566-1925

mehta.suril@epa.gov

From: Reed, Khesha
Sent: Monday, September 21, 2015 3:20 PM
To: Mehta, Suril; Foos, Brenda
Subject: RE: OCHP Staff Meetings

Sorry Suril. I came a little late. Sonda started the call. Not sure what happened.

From: Mehta, Suril
Sent: Monday, September 21, 2015 2:38 PM
To: Reed, Khesha; Foos, Brenda
Subject: Re: OCHP Staff Meetings

I've been on standby. Has the call started?

Suril Mehta

Health Scientist

Regulatory Support and Science Policy Division

Office of Children's Health Protection | US EPA

Ph: 202-566-1925

mehta.suril@epa.gov

From: Reed, Khesha on behalf of Etzel, Ruth
Sent: Monday, September 21, 2015 12:55 PM
To: Mehta, Suril; Schroeder, Kathleen; Firestone, Michael; Belle, Kara; Basden, Phyllis; Merse, Cynthia; Foos, Brenda; Beasley, Ally; Davis, Matthew; Dzubow, Rebecca; Switzer, LaVonne; Miller, Gregory; Berger, Martha; Nahar, Muna; Khoury, Samar; Reed, Khesha; Brown, Margot; White, Sherri; Kukla, Alison; Rice, Nekia; Anderson, BrianO
Cc: Nwana, Chinwude; Saulles, Ariel; Lee, Connie
Subject: OCHP Staff Meetings
When: Monday, September 21, 2015 2:30 PM-3:00 PM.
Where: Conference Room 1144C, WJC West, Conference Call-in **Ex. 6 - Personal Privacy**

Ex. 6 - Personal Privacy

OCHP Staff Meeting Agenda

September 21, 2015

1. Senior Staff Update

2. ISEE Conference Reports – Ally and Muna

3. Thank Yous

4. OCHP Updates

- Continuing to prepare for Children's Health Month. EPA internal communications office will be publicizing our Open House (10/5). We are working to finalize an agenda and location for the Task Force Principal's Meeting (10/14). The Administrator will be visiting a DC area Boys and Girls Club (date TBD). The CHM web page is live. We will continue to add regional events.

- The Administrator is being briefed on the FDA-EPA fish advice tomorrow.

5. General Information/Announcements

- Massive Open Online Course – October 13, 2015. This MOOC was developed by four eminent scientists who together authored the health chapter in the recent 5th Assessment report of the IPCC. They offer you a short crash-course into the topic of climate change, tailored to senior policy-makers and negotiators of climate agreements, particularly as an input into the climate conference COP21 in Paris in December this year. https://iversity.org/en/courses/climate-change-health-for-policy-makers

- BROWN BAG tomorrow (9/22) – to review policy posters. If you are working from home, you can call in and send comments to Khesha, Michelle and Ally.

To: Reed, Khesha[Reed.Khesha@epa.gov]; Foos, Brenda[Foos.Brenda@epa.gov]
From: Mehta, Suril
Sent: Mon 9/21/2015 6:38:07 PM
Subject: Re: OCHP Staff Meetings

I've been on standby. Has the call started?

Suril Mehta

Health Scientist

Regulatory Support and Science Policy Division

Office of Children's Health Protection | US EPA

Ph: 202-566-1925

mehta.suril@epa.gov

From: Reed, Khesha on behalf of Etzel, Ruth
Sent: Monday, September 21, 2015 12:55 PM
To: Mehta, Suril; Schroeder, Kathleen; Firestone, Michael; Belle, Kara; Basden, Phyllis; Merse, Cynthia; Foos, Brenda; Beasley, Ally; Davis, Matthew; Dzubow, Rebecca; Switzer, LaVonne; Miller, Gregory; Berger, Martha; Nahar, Muna; Khoury, Samar; Reed, Khesha; Brown, Margot; White, Sherri; Kukla, Alison; Rice, Nekia; Anderson, BrianO
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Subject: OCHP Staff Meetings
When: Monday, September 21, 2015 2:30 PM-3:00 PM.
Where: Conference Room 1144C, WJC West, Conference **Ex. 6 - Personal Privacy**
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September 21, 2015

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To: Reed, Khesha[Reed.Khesha@epa.gov]
From: Dzubow, Rebecca
Sent: Mon 9/21/2015 5:43:50 PM
Subject: RE: OCHP Staff Meetings

The Administrator is also being briefed on chlorpyrifos tomorrow.

-----Original Appointment-----
From: Reed, Khesha **On Behalf Of** Etzel, Ruth
Sent: Monday, September 21, 2015 12:56 PM
To: Mehta, Suril; Schroeder, Kathleen; Firestone, Michael; Belle, Kara; Basden, Phyllis; Merse, Cynthia; Foos, Brenda; Beasley, Ally; Davis, Matthew; Dzubow, Rebecca; Switzer, LaVonne; Miller, Gregory; Berger, Martha; Nahar, Muna; Khoury, Samar; Reed, Khesha; Brown, Margot; White, Sherri; Kukla, Alison; Rice, Nekia; Anderson, BrianO
Cc: Nwana, Chinwude; Saulles, Ariel; Lee, Connie
Subject: OCHP Staff Meetings
When: Monday, September 21, 2015 2:30 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Conference Room 1144C, WJC West, Conference **Ex. 6 - Personal Privacy**
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OCHP Staff Meeting Agenda
September 21, 2015

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3. Thank Yous
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* BROWN BAG tomorrow (9/22) - to review policy posters. If you are working from home, you can call in and send comments to Khesha, Michelle and Ally.

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: Curtis, Mellasonda
Sent: Wed 9/14/2016 8:22:47 PM
Subject: FW: NHANES special study on children and EPA-FDA fish advice

FYI…Sonda

From: Larimer, Lisa
Sent: Wednesday, September 14, 2016 4:22 PM
To: Curtis, Mellasonda <Curtis.Mellasonda@epa.gov>
Subject: RE: NHANES special study on children and EPA-FDA fish advice

Great. I'm trying to wrap up things before I'm out of the office for the rest of the week, so I've asked Evelyn McRae to work with you on this.

Thanks,

Lisa

From: Curtis, Mellasonda
Sent: Wednesday, September 14, 2016 3:01 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: NHANES special study on children and EPA-FDA fish advice

Ms. Larimer,

Ruth has a fair amount of time from the Sept. 27th – 30th. So I ask that you provide me with your available times and I will merge your schedules.

Thank you,

Mellasonda Curtis

Office of Children's Health Protection

US Environmental Protection Agency

1301 Constitution Avenue NW (1144E)

Washington, DC 20460

Tele: 202-566-9971

Main#: 202-564-2188

Fax: 202-564-2733

From: Larimer, Lisa
Sent: Tuesday, September 13, 2016 4:39 PM
To: Curtis, Mellasonda <Curtis.Mellasonda@epa.gov>
Subject: RE: NHANES special study on children and EPA-FDA fish advice

Good afternoon,

That day and time would be challenging. I understand that Ruth will be out of the office for a bit after that. When would there be another available time?

Lisa Larimer, P.E. | **Team Leader**

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Curtis, Mellasonda
Sent: Tuesday, September 13, 2016 12:55 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: FW: NHANES special study on children and EPA-FDA fish advice

Good afternoon Ms. Larimer,

I manage Ruth Etzel's schedule and she has some time available on Sept. 19th from 9:00 – 9:45 a.m. to have this meeting. Let me know if timeframe works for you?

Thank you,

Mellasonda Curtis

Office of Children's Health Protection

US Environmental Protection Agency

1301 Constitution Avenue NW (1144E)

Washington, DC 20460

Tele: 202-566-9971

Main#: 202-564-2188

Fax: 202-564-2733

From: Reed, Khesha
Sent: Tuesday, September 13, 2016 11:46 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Curtis, Mellasonda <Curtis.Mellasonda@epa.gov>
Subject: RE: NHANES special study on children and EPA-FDA fish advice

Sorry Lisa. I didn't get your email until after the 1:30 meeting yesterday. Yes, we would be very interested in an update on the FDA-EPA fish advise. I would like to include my new office director, Ruth Etzel, and a few people on our staff. I am copying Sonda Curtis, Ruth's scheduler, to find a date/time. Unfortunately Ruth will be out of the office for much of the next couple of weeks. If we can't squeeze it in on the 19th, we will have to wait until the week of 9/26.

Sonda – please also include Ted and Michael. Me, Brenda and Martha can be optional.

Thanks,

Khesha Reed

Associate Director

Office of Children's Health Protection

202-566-0594

From: Larimer, Lisa
Sent: Monday, September 12, 2016 11:33 AM
To: Reed, Khesha <Reed.Khesha@epa.gov>
Subject: NHANES special study on children and EPA-FDA fish advice

Good morning Khesha,

I would like to alert you to an opportunity and touch base with you on the fish advice for women and children.

NHANES special study

Ex. 5 - Deliberative Process

If you would like someone from your staff to join the call, I can send the agenda and call-in information when I receive it. (I just found out about this Friday.) Just let me know to whom to send it.

EPA-FDA fish advice

The FDA-EPA workgroup has had the technical underpinnings of the advice for women and children on consuming fish with mercury peer reviewed. While we are still responding to peer review comments, we are making adjustments to the advice. I'd like to update you and/or your staff on developments, ideally in the next week or two. Please let me know who should attend and I will get a meeting set up.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: InsideEPA.com
Sent: Wed 8/24/2016 5:30:07 PM
Subject: Today's Must-Read News

August 24, 2016

Today's Must-Read News

EPA Increases Burden On States For Tracking Title V Air Permit Objections

EPA is proposing to increase the burden on states for tracking objections to Clean Air Act Title V permits by mandating that states provide written responses to comments on permits they issue under delegated air law authority and submit those records to the agency, which has ultimate power to approve or reject a state-issued permit.

New Peer Review Further Delays Final EPA-FDA Fish Consumption Advisory

The Food and Drug Administration (FDA) has initiated another peer review related to the joint advisory that EPA and FDA released in 2014 recommending amounts of fish that pregnant women and those who may be pregnant should eat, and a former FDA source says it is unlikely the long-delayed update will be finished before the end of the year.

EDITORIAL CONTACT

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Mailing address: 1919 South Eads Street, Suite 201, Arlington VA 22202

Telephone: 703-416-8500 or 1-800-424-9068

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: InsideEPA.com
Sent: Tue 8/23/2016 11:50:02 AM
Subject: Risk Policy Report - Latest Issue Now Available

August 23, 2016

Now Available: *Risk Policy Report*

Top Stories

New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory

The Food and Drug Administration (FDA) has initiated another peer review related to the joint advisory that EPA and FDA released in 2014 recommending amounts of fish that pregnant women and those who may be pregnant should eat, though a former FDA source says that it is unlikely the long-stalled update will be completed before year's end.

Industry Urges OSHA To Halt PSM Update, Citing Limited Power, EPA Fears

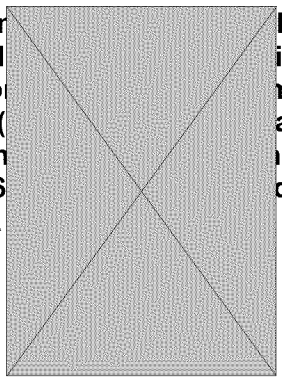
Chemical and petroleum industry groups are urging the Occupational Safety and Health Administration (OSHA) to halt or minimize potential revisions to its process safety management (PSM) rule, raising new arguments that the agency lacks statutory authority for some possible changes, while urging officials to streamline any new requirements with upcoming EPA rules.

Some Reviewers Urge EPA To Add New Approaches To Draft Exposure Guide

Some of the experts who are peer reviewing EPA's proposed update to its 24-year-old human exposure assessment guidelines are pressing the agency to address current and emerging analytical methods, a call which could delay EPA's efforts to quickly finalize the long-running effort to update the guidelines.

TSCA Reform Law Could Spur EPA, States To Increase Enforcement Efforts

Cher ls and environmentalists are pred ick in state and EPA enfo med Toxic Substances Control Act (ad new authorities that the agen e law, compared to the prior 1976 d few regulatory actions that EPA



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Mailing address: 1919 South Eads Street, Suite 201, Arlington VA 22202

Telephone: 703-416-8500 or 1-800-424-9068

To: Curtis, Mellasonda[Curtis.Mellasonda@epa.gov]; Reed, Khesha[Reed.Khesha@epa.gov]
From: Miller, Gregory
Sent: Mon 8/1/2016 6:12:12 PM
Subject: OCHP Transition ideas

I chose to focus my brainstorming of opportunities on "Children's Environmental Health Issues that concern me as a parent".

Ex. 5 - Deliberative Process

•□□□□□□□□ Fish consumption advice for pregnant women and nursing mothers

Greg Miller

Office of Children's Health Protection

US Environmental Protection Agency

1200 Pennsylvania Ave, NW (MC 1107T)

Washington, DC 20460

phone: (202) 566-2310

fax: (202) 564-2733

****

Sign up for the US EPA Children's Environmental Health Listserv

****

To: Blaine, Susan[Susan.Blaine@icfi.com]
Cc: Reed, Khesha[Reed.Khesha@epa.gov]; Foos, Brenda[Foos.Brenda@epa.gov]; Mapp, Latisha[Mapp.Latisha@epa.gov]
From: Berger, Martha
Sent: Wed 3/30/2016 1:59:24 PM
Subject: Re: Update of Joint EPA/FDA Fish Consumption Advice

Thanks! The webpage on letters is beautiful!

Martha
Martha Berger
Office of Children's Health Protection
US Environmental Protection Agency
202/564-2191 office
202/230-4784 cell

On Mar 30, 2016, at 9:57 AM, Blaine, Susan <Susan.Blaine@icfi.com> wrote:

Martha,

Yes, I am coordinating with GW about the building tour. It seems to be a "go," but we're awaiting final confirmation from the person giving the tour.

And yes, the ***NEW*** and improved letters page is LIVE!!
https://www.epa.gov/children/childrens-health-protection-advisory-committee-chpac.

Best,

Susan

SUSAN BLAINE, CMP, CGMP | Senior Associate, Certified Meeting Planner | 703.225.2471 (o) | susan.blaine@icfi.com

From: Berger, Martha [mailto:Berger.Martha@epa.gov]
Sent: Wednesday, March 30, 2016 8:49 AM
To: Reed, Khesha <Reed.Khesha@epa.gov>; Foos, Brenda <Foos.Brenda@epa.gov>; Mapp, Latisha <Mapp.Latisha@epa.gov>
Cc: Blaine, Susan <Susan.Blaine@icfi.com>

Subject: Fwd: Update of Joint EPA/FDA Fish Consumption Advice

As we suspected, so this is off the table for CHPAC in May.

Susan, I didn't have a chance yesterday to ask about the building tour or when the letters page change will be made. We can talk today or tomorrow if you like. I'm on my cell.

Martha

Martha Berger

Office of Children's Health Protection

US Environmental Protection Agency

202/564-2191 office

202/230-4784 cell

Begin forwarded message:

> **From:** "Coopwood, Theodore" <Coopwood.Theodore@epa.gov>
> **Date:** March 30, 2016 at 8:38:20 AM EDT
> **To:** "Wathen, John" <Wathen.John@epa.gov>, "Larimer, Lisa" <Larimer.Lisa@epa.gov>
> **Cc:** "Berger, Martha" <Berger.Martha@epa.gov>, "Barash, Shari" <Barash.Shari@epa.gov>, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
> **Subject: Re: Update of Joint EPA/FDA Fish Consumption Advice**
>
> Thank John,
>
> I appreciate the update
>
> Ted

From: Wathen, John
Sent: Wednesday, March 30, 2016 8:27 AM
To: Coopwood, Theodore; Larimer, Lisa
Cc: Berger, Martha; Barash, Shari; Southerland, Elizabeth
Subject: RE: Update of Joint EPA/FDA Fish Consumption Advice

Ted-

Right now, we are dead in the water. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process We and FDA staff are ready to move ahead with peer review, as is our management in OW, but we have not heard a peep from FDA management. You could say the ball is in their court.

That's about all I know. We know that there is a lot of interest in moving ahead with the advice, and we have done all we can to advance the ball.

~John

From: Coopwood, Theodore
Sent: Wednesday, March 30, 2016 7:59 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Berger, Martha <Berger.Martha@epa.gov>
Subject: Update of Joint EPA/FDA Fish Consumption Advice

Good morning Lisa and John,

I trust you both are doing well. I would appreciate any information you can provide on the current status of the Joint EPA/FDA Fish Consumption Advice. I

know this is short notice, but if you could possibly get something to me by this afternoon, that would be excellent.

Thanks for your help and I look forward to hearing from you soon,

Ted

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: Berger, Martha
Sent: Wed 3/16/2016 6:02:02 PM
Subject: RE: EWG Hair Mercury study

Great idea, thanks.

Martha Berger

Office of Children's Health Protection

US Environmental Protection Agency

202/564-2191

From: Reed, Khesha
Sent: Wednesday, March 16, 2016 2:01 PM
To: Berger, Martha <Berger.Martha@epa.gov>
Subject: Re: EWG Hair Mercury study

I think the response if fine also. Does ODACMO have any guidance or policy? Maybe you can find out tomorrow at the DFO meeting. It might be a good idea to ask Barbara to hold off for a day.

Sent from my iPhone

On Mar 16, 2016, at 1:45 PM, Berger, Martha <Berger.Martha@epa.gov> wrote:

> Hi,
>
> I think Barb's proposed response is fine, but am not sure what else to say regarding procedure for stuff like this. Do you have any thoughts?
>
> Martha

Martha Berger

Office of Children's Health Protection

US Environmental Protection Agency

202/564-2191

From: Morrissey, Barbara (DOH) [mailto:Barbara.Morrissey@DOH.WA.GOV]
Sent: Wednesday, March 16, 2016 1:41 PM
To: Berger, Martha <Berger.Martha@epa.gov>
Subject: RE: EWG Hair Mercury study

Hi Martha, we haven't reviewed the procedures you would like me to follow when I get an email partly because I am the CHPAC chair. Here is a recent email I received from EWG. It mixes my role at WA state toxicology with my role as CHPAC lead. Here is my draft response. Could you let me know 1) how you would prefer I handle future emails of this nature and 2) if the response below is OK ?

Thanks, Barb

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Best Regards,

Barbara Morrissey, MS | Toxicologist
Office of Environmental Public Health Sciences
Washington State Department of Health
PO Box 47825
Olympia, WA 98504-7825
(360) 236-3368
Physical Location: 243 Israel Rd SE, Tumwater

Chair, Children's Health Protection Advisory Committee to the U.S. Enviornmental Protection Agency

https://www.epa.gov/children/childrens-health-protection-advisory-committee-chpac

From: Sonya Lunder [mailto:sonya@ewg.org]
Sent: Wednesday, March 16, 2016 9:59 AM
To: Morrissey, Barbara (DOH)
Subject: EWG Hair Mercury study

Ms. Morrissey,

I am attaching a study Environmental Working Group released today finding high mercury exposures for American women who eat 2 or more seafood meals per week. I thought it would be of interest to you both as the chair of the EPA CHEPAC committee, as well as Washington's great work on mercury in fish.

Thank you,

Sonya

Today EWG and the Mercury Policy Project are releasing results of a study measuring mercury levels in hair samples from women who eat two or more seafood meals per week. We found that 29% exceed the EPA guideline for mercury exposure during pregnancy (1 part per million), and 59% exceed a more protective upper limit of 0.58 ppm recommended by Philippe Grandjean and colleagues. Tuna sushi, steaks and in cans was a major source of mercury exposure for participants (40% of estimated ingestion)

We are concerned that the draft seafood advice from the FDA and EPA is incomplete. It urges pregnant women to dramatically increase seafood consumption but doesn't provide enough detail about moderate and high mercury species to limit or avoid during pregnancy.

Notably only 17% of mercury in participants' diets was the species FDA and EPA name in the draft advice. Furthermore based on dietary surveys we estimated that 59% of our study participants didn't ingest the optimal amount of omega-3s recommended during pregnancy (250 mg DHA+EPA per day)

You can read the report online or download a pdf at: http://www.ewg.org/research/us-fish-advice-may-expose-babies-too-much-mercury/executive-summary

<image001.png>

Sonya Lunder, MPH

Environmental Working Group

Washington DC 20009

Sonya@ewg.org

202/939-9129

To: Reed, Khesha[Reed.Khesha@epa.gov]
From: Berger, Martha
Sent: Wed 3/16/2016 5:45:22 PM
Subject: FW: EWG Hair Mercury study

Hi,

I think Barb's proposed response is fine, but am not sure what else to say regarding procedure for stuff like this. Do you have any thoughts?

Martha

Martha Berger

Office of Children's Health Protection

US Environmental Protection Agency

202/564-2191

From: Morrissey, Barbara (DOH) [mailto:Barbara.Morrissey@DOH.WA.GOV]
Sent: Wednesday, March 16, 2016 1:41 PM
To: Berger, Martha <Berger.Martha@epa.gov>
Subject: RE: EWG Hair Mercury study

Hi Martha, we haven't reviewed the procedures you would like me to follow when I get an email partly because I am the CHPAC chair. Here is a recent email I received from EWG. It mixes my role at WA state toxicology with my role as CHPAC lead. Here is my draft response. Could you let me know 1) how you would prefer I handle future emails of this nature and 2) if the response below is OK ?

Thanks, Barb

Ex. 5 - Deliberative Process

Best Regards,

Barbara Morrissey, MS | Toxicologist
Office of Environmental Public Health Sciences
Washington State Department of Health
PO Box 47825
Olympia, WA 98504-7825
(360) 236-3368
Physical Location: 243 Israel Rd SE, Tumwater

Chair, Children's Health Protection Advisory Committee to the U.S. Enviornmental Protection Agency

https://www.epa.gov/children/childrens-health-protection-advisory-committee-chpac

From: Sonya Lunder [mailto:sonya@ewg.org]
Sent: Wednesday, March 16, 2016 9:59 AM
To: Morrissey, Barbara (DOH)

Subject: EWG Hair Mercury study

Ms. Morrissey,

I am attaching a study Environmental Working Group released today finding high mercury exposures for American women who eat 2 or more seafood meals per week. I thought it would be of interest to you both as the chair of the EPA CHEPAC committee, as well as Washington's great work on mercury in fish.

Thank you,

Sonya

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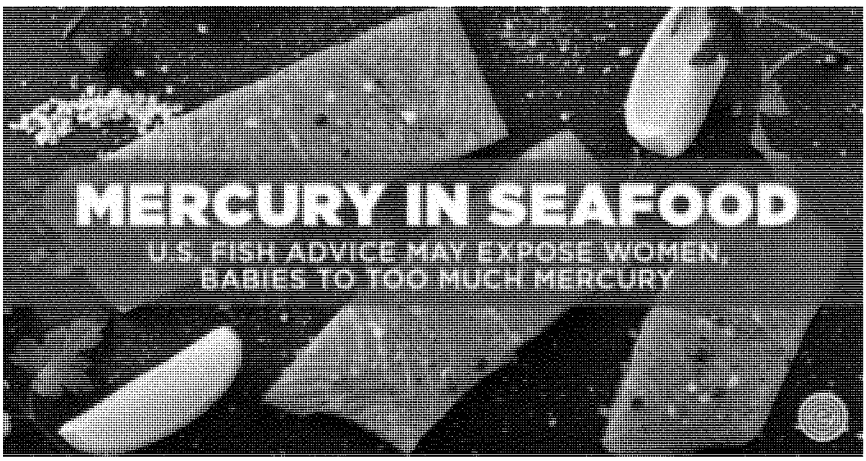
We are concerned that the draft seafood advice from the FDA and EPA is incomplete. It urges pregnant women to dramatically increase seafood consumption but doesn't provide enough detail about moderate and high mercury species to limit or avoid during pregnancy.

Notably only 17% of mercury in participants' diets was the species FDA and EPA name in the draft advice. Furthermore based on dietary surveys we estimated that 59% of our study participants didn't ingest the optimal amount of omega-3s recommended during pregnancy (250 mg DHA+EPA per day)

You can read the report online or download a pdf at: http://www.ewg.org/research/us-fish-advice-may-expose-babies-too-much-mercury/executive-summary



Sonya Lunder, MPH

Environmental Working Group

Washington DC 20009

Sonya@ewg.org

202/939-9129

To: Curtis, Mellasonda[Curtis.Mellasonda@epa.gov]
From: Reed, Khesha
Sent: Mon 9/21/2015 8:17:16 PM
Subject: Fwd: Materials for FDA-EPA Fish Advice briefing

It looks like they added one more attachment for the FDA meeting tomorrow.

Sent from my iPhone

Begin forwarded message:

From: "Larimer, Lisa" <Larimer.Lisa@epa.gov>
To: "Wathen, John" <Wathen.John@epa.gov>, "Hisel-Mccoy, Sara" <Hisel-McCoy.Sara@epa.gov>, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>, "Burke, Thomas" <Burke.Thomas@epa.gov>, "Etzel, Ruth" <Etzel.Ruth@epa.gov>, "Coopwood, Theodore" <Coopwood.Theodore@epa.gov>, "Mitchell, Stacey" <Mitchell.Stacey@epa.gov>, "Schroer, Lee" <schroer.lee@epa.gov>, "Klasen, Matthew" <Klasen.Matthew@epa.gov>, "Ingram, Amir" <Ingram.Amir@epa.gov>
Cc: "Loop, Travis" <Loop.Travis@epa.gov>, "Lalley, Cara" <Lalley.Cara@epa.gov>, "Kavlock, Robert" <Kavlock.Robert@epa.gov>, "Hauchman, Fred" <hauchman.fred@epa.gov>, "Schoeny, Rita" <Schoeny.Rita@epa.gov>, "Reed, Khesha" <Reed.Khesha@epa.gov>, "Firestone, Michael" <Firestone.Michael@epa.gov>, "Penman, Crystal" <Penman.Crystal@epa.gov>, "Gentry, Nathan" <Gentry.Nathan@epa.gov>, "Foos, Brenda" <Foos.Brenda@epa.gov>, "Conerly, Octavia" <Conerly.Octavia@epa.gov>
Subject: Materials for FDA-EPA Fish Advice briefing

Ken

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Reed, Khesha
Sent: Mon 9/21/2015 7:41:09 PM
Subject: Re: fish advice (horizontal & vertical charts and Q&A)

No. Only the meeting request form is attached to the meeting notice. If you can send the power point to me I would appreciate it.

Khesha

Sent from my iPhone

On Sep 21, 2015, at 3:38 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

> Did you say you were able to pull a copy of the powerpoint off the meeting invite? I ask because I don't see it and will send out if it's not there.
>
> **From:** Reed, Khesha
> **Sent:** Monday, September 21, 2015 3:38 PM
> **To:** Larimer, Lisa
> **Subject:** Re: fish advice (horizontal & vertical charts and Q&A)
>
> Thanks!
>
> Sent from my iPhone
>
> On Sep 21, 2015, at 3:30 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:
>
> Khesha-

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

<FISH_CHART_V_9.2.pdf>

<FISH_CHART_H_9.2.pdf>

<Fish Advice Qs and As-8 24 15 clean with comment box for NIH and placeholder for diagram.docx>

To: Curtis, Mellasonda[Curtis.Mellasonda@epa.gov]
From: Reed, Khesha
Sent: Mon 9/21/2015 7:38:51 PM
Subject: Fwd: fish advice (horizontal & vertical charts and Q&A)
FISH_CHART_V_9.2.pdf
ATT00001.htm
FISH_CHART_H_9.2.pdf
ATT00002.htm
Fish Advice Qs and As-8 24 15 clean with comment box for NIH and placeholder for diagram.docx
ATT00003.htm

Can you print these for Ruth's meeting tomorrow?

Sent from my iPhone

Begin forwarded message:

From: "Larimer, Lisa" <Larimer.Lisa@epa.gov>
Date: September 21, 2015 at 3:30:12 PM EDT
To: "Reed, Khesha" <Reed.Khesha@epa.gov>
Subject: fish advice (horizontal & vertical charts and Q&A)

Khesha-

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Mehta, Suril[Mehta.Suril@epa.gov]; Foos, Brenda[Foos.Brenda@epa.gov]
From: Reed, Khesha
Sent: Mon 9/21/2015 7:20:59 PM
Subject: RE: OCHP Staff Meetings

Sorry Suril. I came a little late. Sonda started the call. Not sure what happened.

From: Mehta, Suril
Sent: Monday, September 21, 2015 2:38 PM
To: Reed, Khesha; Foos, Brenda
Subject: Re: OCHP Staff Meetings

I've been on standby. Has the call started?

Suril Mehta

Health Scientist

Regulatory Support and Science Policy Division

Office of Children's Health Protection | US EPA

Ph: 202-566-1925

mehta.suril@epa.gov

From: Reed, Khesha on behalf of Etzel, Ruth
Sent: Monday, September 21, 2015 12:55 PM
To: Mehta, Suril; Schroeder, Kathleen; Firestone, Michael; Belle, Kara; Basden, Phyllis; Merse, Cynthia; Foos, Brenda; Beasley, Ally; Davis, Matthew; Dzubow, Rebecca; Switzer, LaVonne; Miller, Gregory; Berger, Martha; Nahar, Muna; Khoury, Samar; Reed, Khesha; Brown, Margot; White, Sherri; Kukla, Alison; Rice, Nekia; Anderson, BrianO
Cc: Nwana, Chinwude; Saulles, Ariel; Lee, Connie
Subject: OCHP Staff Meetings
When: Monday, September 21, 2015 2:30 PM-3:00 PM.
Where: Conference Room 1144C, WJC West, Conference Ex. 6 - Personal Privacy

Ex. 6 - Personal Privacy

OCHP Staff Meeting Agenda

September 21, 2015

1. Senior Staff Update

2. ISEE Conference Reports – Ally and Muna

3. Thank Yous

4. OCHP Updates

- Continuing to prepare for Children's Health Month. EPA internal communications office will be publicizing our Open House (10/5). We are working to finalize an agenda and location for the Task Force Principal's Meeting (10/14). The Administrator will be visiting a DC area Boys and Girls Club (date TBD). The CHM web page is live. We will continue to add regional events.

- The Administrator is being briefed on the FDA-EPA fish advice tomorrow.

5. General Information/Announcements

- Massive Open Online Course – October 13, 2015. This MOOC was developed by four eminent scientists who together authored the health chapter in the recent 5th Assessment report of the IPCC. They offer you a short crash-course into the topic of climate change, tailored to senior policy-makers and negotiators of climate agreements, particularly as an input into the climate conference COP21 in Paris in December this year. https://iversity.org/en/courses/climate-change-health-for-policy-makers

- BROWN BAG tomorrow (9/22) – to review policy posters. If you are working from home, you can call in and send comments to Khesha, Michelle and Ally.

To: Berger, Martha[Berger.Martha@epa.gov]
From: Reed, Khesha
Sent: Mon 7/20/2015 8:20:07 PM
Subject: Re: Would like to update someone in CHPO on EPA-FDA fish advisory progress

FYI - Ted is out all week.

Sent from my iPhone

On Jul 20, 2015, at 2:30 PM, Berger, Martha <Berger.Martha@epa.gov> wrote:

Ted,

Can you follow up with Lisa about this, please? I think plenty of ochp folks would be happy to sit in on the briefing, so unless there are objections, I would recommend a general invite to the office.

Thanks,

Martha

Martha Berger

Office of Children's Health Protection

US Environmental Protection Agency

202/564-2191

From: Larimer, Lisa
Sent: Friday, July 17, 2015 11:57 AM
To: Berger, Martha
Subject: Would like to update someone in CHPO on EPA-FDA fish advisory progress

Hi Martha,

This is a bit of a shot in the dark because I'm relatively new to the fish advice work and I'm not sure who, if anyone, our office has contacted in the past about this. The workgroup has reviewed comments from the public on the 2014 draft version of the fish advisory for pregnant women and children and has almost finalized everything. We received comments from the Children's Health Protection Advisory Committee, and I found your name associated with that committee. We are not looking to meet with CHPAC itself but would like to meet with someone, probably at the staff level, in the Children's Health Protection Office to let them know what the final version of the advice is likely to look like and how we addressed CHPAC's comments.

If you could let me know if you are the correct person, or if not then who is, and I'd be happy to set up a meeting with my team. We'd like to do it before we brief our AA on July 30.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Reed, Khesha
Location: DCRoomARN3530CFTB/DC-Ariel-Rios-AO
Importance: Normal
Subject: Accepted: FDA-EPA Fish Advice
Start Date/Time: Thur 9/17/2015 9:00:00 PM
End Date/Time: Thur 9/17/2015 9:45:00 PM

To: Foos, Brenda[Foos.Brenda@epa.gov]; Margot (Brown.Margot@epa.gov)[Brown.Margot@epa.gov]; Coopwood, Theodore[Coopwood.Theodore@epa.gov]; Martha Berger[Berger.Martha@epa.gov]
From: Reed, Khesha
Sent: Wed 12/10/2014 5:30:39 PM
Subject: FW: CHPAC letter on FDA-EPA Fish Advisory

FYI-

From: Reed, Khesha
Sent: Wednesday, December 10, 2014 12:30 PM
To: Hawkins, Denise; Southerland, Elizabeth
Cc: Hisel-Mccoy, Sara; Bigler, Jeff
Subject: RE: CHPAC letter on FDA-EPA Fish Advisory

Thanks. This helps. I'll keep an eye out for another FR notice and I will inform the CHPAC that the comment period could close as early as January 1st.

Khesha Reed

Associate Director

Office of Children's Health Protection

Environmental Protection Agency
1200 Pennsylvania Ave, NW
Mailcode 1107T
Washington, DC 20460

(202) 566-0594

From: Hawkins, Denise
Sent: Tuesday, December 09, 2014 5:41 PM
To: Reed, Khesha; Southerland, Elizabeth
Cc: Hisel-Mccoy, Sara; Bigler, Jeff
Subject: RE: CHPAC letter on FDA-EPA Fish Advisory

Khesha,

When FDA issued the draft advisory, they indicated that the comment period would be open until 30 days after the last transcript from the advisory committee meeting and any other public meetings became available. They said they would publish a notice in the Federal Register to announce that date.

We recently saw that the transcript of their November public meeting was posted online on December 1. We aren't aware that they plan to hold any additional meetings. Given that, it seems like they could close the comment period as early as January 1. Hope this helps. If we learn more, we'll certainly let you know.

Denise

From: Reed, Khesha
Sent: December 09, 2014 3:43 PM
To: Southerland, Elizabeth
Cc: Hawkins, Denise
Subject: CHPAC letter on FDA-EPA Fish Advisory

I wanted to give you an update. The CHPAC meet last week. They have drafted a letter to the Administrator regarding the advisory but were not able to finalize it. I think they will be finished in early January.

Do you know when FDA comment period closes? I want to make sure that they send the letter while the docket is open.

Thanks,

Khesha Reed

Associate Director

Office of Children's Health Protection

Environmental Protection Agency
1200 Pennsylvania Ave, NW
Mailcode 1107T
Washington, DC 20460

(202) 566-0594

To: Coopwood, Theodore[Coopwood.Theodore@epa.gov]; Firestone, Michael[Firestone.Michael@epa.gov]
Cc: Martha Berger[Berger.Martha@epa.gov]; Foos, Brenda[Foos.Brenda@epa.gov]
From: Reed, Khesha
Sent: Wed 9/14/2016 8:28:53 PM
Subject: FW: NHANES special study on children and EPA-FDA fish advice

FYI – Sonda is working with OW to schedule an EPA-FDA fish advice update. It won't happen until the week of 9/26.

From: Larimer, Lisa
Sent: Monday, September 12, 2016 11:33 AM
To: Reed, Khesha <Reed.Khesha@epa.gov>
Subject: NHANES special study on children and EPA-FDA fish advice

Good morning Khesha,

I would like to alert you to an opportunity and touch base with you on the fish advice for women and children.

NHANES special study

Ex. 5 - Deliberative Process

If you would like someone from your staff to join the call, I can send the agenda and call-in information when I receive it. (I just found out about this Friday.) Just let me know to whom to send it.

EPA-FDA fish advice

The FDA-EPA workgroup has had the technical underpinnings of the advice for women and children on consuming fish with mercury peer reviewed. While we are still responding to peer review comments, we are making adjustments to the advice. I'd like to update you and/or your staff on developments, ideally in the next week or two. Please let me know who should attend and I will get a meeting set up.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
Cc: Hawkins, Denise[Hawkins.Denise@epa.gov]; Hisel-Mccoy, Sara[Hisel-McCoy.Sara@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Washington, Evelyn[Washington.Evelyn@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Martha Berger[Berger.Martha@epa.gov]
From: Reed, Khesha
Sent: Tue 8/19/2014 1:22:49 PM
Subject: RE: Children's Health Protection Advisory Committee

Thanks.

We are finalizing the agenda now. We'll work directly with Jeff to confirm a time.

Khesha Reed

Acting Director

Office of Children's Health Protection

Environmental Protection Agency
1200 Pennsylvania Ave, NW
Mailcode 1107T
Washington, DC 20460

(202) 566-0594

From: Southerland, Elizabeth
Sent: Tuesday, August 19, 2014 9:08 AM
To: Reed, Khesha
Cc: Hawkins, Denise; Hisel-Mccoy, Sara; Wathen, John; Washington, Evelyn; Bigler, Jeff
Subject: Re: Children's Health Protection Advisory Committee

We are fine with the draft charge. Jeff Bigler will give the presentation. The key document is the Dietary Guideline but other related documents are also referenced in the Qa&As. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Sent from my iPhone

On Aug 18, 2014, at 5:27 PM, "Reed, Khesha" <Reed.Khesha@epa.gov> wrote:

Betsey,

I heard back from FDA. They are fine with CHPAC providing advice on the Fish Advisory. They even approved the charge!

Can you take a closer look at the draft charge below and make sure OW is OK with it as well? I basically cut and pasted language from the FR notice. It seems that FDA would prefer that EPA handle the presentation to the CHPAC on the topic. Can you suggest someone that can do a background briefing on the joint draft advisory and discuss the studies most relevant to the decisions on orange roughy/marlin and young children's fish consumption. Are there any documents that outline the FDA/EPA analysis? Any documentation that you can provide that helped the agencies establish the recommendations in the updated draft would be helpful.

We are behind schedule in finalizing the agenda, so a quick response would be greatly appreciated.

Please give me a call if you have questions. Thanks for your help.

Khesha Reed

Acting Director

Office of Children's Health Protection

Environmental Protection Agency
1200 Pennsylvania Ave, NW
Mailcode 1107T
Washington, DC 20460

(202) 566-0594

From: Reed, Khesha
Sent: Thursday, August 14, 2014 7:03 PM
To: Southerland, Elizabeth
Subject: Re: Children's Health Protection Advisory Committee

Ex. 5 - Deliberative Process

Hopefully I'll hear back from her tomorrow. I really need to finalize the agenda.

I'll keep you informed.

Sent from my iPhone

On Aug 14, 2014, at 3:35 PM, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov> wrote:

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Sent: Thursday, August 14, 2014 2:23 PM
To: Southerland, Elizabeth
Subject: FW: Children's Health Protection Advisory Committee

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(202) 566-0594

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To: 'Natanblut, Sharon'
Subject: RE: Children's Health Protection Advisory Committee

Sharon,

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Sent: Monday, August 11, 2014 3:32 PM
To: Reed, Khesha
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Thanks.

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Ex. 5 - Deliberative Process

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Sharon Natanblut

Director, Strategic Communications and Public Engagement

FDA Foods and Veterinary Medicine Directorate

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Acting Director

Office of Children's Health Protection

(202) 566-0594

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Ex. 5 - Deliberative Process

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Also, we had some other questions:

Ex. 5 - Deliberative Process

We realize the meeting is less than a month away and so we want to be able to get back to you as soon as possible. If you would find it easier for us to have a call to discuss the questions above, we would be pleased to arrange that.

Many thanks.

Sharon Natanblut

Director, Strategic Communications and Public Engagement

FDA Foods and Veterinary Medicine Directorate

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We are currently drafting the agenda for the September meeting and welcome your feedback as we determine if it should include the fish advisory now or table the topic for a joint meeting.

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Thank you,

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Acting Director

Office of Children's Health Protection

(202) 566-0594

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Reed, Khesha
Sent: Mon 8/18/2014 8:03:42 PM
Subject: RE: Children's Health Protection Advisory Committee

I understand. I am free for the rest of the afternoon. Look forward to hearing from you.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, August 18, 2014 3:58 PM
To: Reed, Khesha
Subject: RE: Children's Health Protection Advisory Committee

Khesha, I'm so sorry – I've been trying all day. I will do so again.

Sharon

From: Reed, Khesha [mailto:Reed.Khesha@epa.gov]
Sent: Monday, August 18, 2014 11:09 AM
To: Natanblut, Sharon
Subject: RE: Children's Health Protection Advisory Committee

I have a CHPAC Steering Committee Meeting at noon. Can we talk before then?

Khesha Reed

Acting Director

Office of Children's Health Protection

Environmental Protection Agency
1200 Pennsylvania Ave, NW
Mailcode 1107T
Washington, DC 20460

(202) 566-0594

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Friday, August 15, 2014 6:36 PM
To: Reed, Khesha
Subject: RE: Children's Health Protection Advisory Committee

Khesha,

My hope is that we can talk Monday – early in the day. I totally understand your need to finalize the agenda.

Have a good weekend. Please email me on Monday if you don't hear from me when you need to.

Sharon

From: Reed, Khesha [mailto:Reed.Khesha@epa.gov]
Sent: Friday, August 15, 2014 4:30 PM
To: Natanblut, Sharon
Subject: RE: Children's Health Protection Advisory Committee

Sharon,

When do you think you might be able to give me feedback? We need to finalize the agenda as soon as possible.

I am working from home today. You can reach me on my cell phone if you have questions.

Thanks,

Khesha

Ex. 6 - Personal Privacy

From: Reed, Khesha
Sent: Tuesday, August 12, 2014 5:19 PM
To: Natanblut, Sharon
Subject: RE: Children's Health Protection Advisory Committee

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Ex. 5 - Deliberative Process

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Acting Director

Office of Children's Health Protection

(202) 566-0594

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Reed, Khesha
Sent: Thur 8/14/2014 11:03:10 PM
Subject: Re: Children's Health Protection Advisory Committee

I don't understand either. It seems that they are hung up on the fact that we didn't specifically say that the CHPAC would review years ago and it was not specifically outlined in the FR notice.

Hopefully I'll hear back from her tomorrow. I really need to finalize the agenda.

I'll keep you informed.

Sent from my iPhone

On Aug 14, 2014, at 3:35 PM, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov> wrote:

> I don't know why FDA is so concerned about this since all federal agencies have external committees to advise them. I explained to Sharon Natanblut that the Deputy Administrator directed you to proceed with this review as an independent body separate from the Office of Water.
>
> **From:** Reed, Khesha
> **Sent:** Thursday, August 14, 2014 2:23 PM
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Subject: RE: Children's Health Protection Advisory Committee

Hi Khesha,

We do have several requests for information with regard to the September meeting and would greatly appreciate if you could provide the following:

1. the FR notice issued about the September meeting (as well as any other info made public about this meeting)

2. the list of questions you are planning to ask the committee to consider.

3. the agenda (or are you still developing it) – is the entire meeting devoted to the seafood advice or is it just one topic

Also, we had some other questions:

1. Have you reached out to CHPAC members yet to ask who wants to be on the workgroup? And would the workgroup do any work prior to the meeting or would they get an assignment following the meeting?

2. Once the report is provided to the Administrator, does she review and then comment on it? Did you say that report would be submitted by the Administrator to the docket for seafood advice?

3. Would the committee and/or the workgroup examine the question posed in the FR notice in terms of what new studies would be needed going forward to provide future advice or based on the currently available studies what does the committee think of the proposed advice?

We realize the meeting is less than a month away and so we want to be able to get back to you as soon as possible. If you would find it easier for us to have a call to discuss the questions above, we would be pleased to arrange that.

Many thanks.

Sharon Natanblut

Director, Strategic Communications and Public Engagement

FDA Foods and Veterinary Medicine Directorate

From: Reed, Khesha [mailto:Reed.Khesha@epa.gov]
Sent: Wednesday, August 06, 2014 5:43 PM
To: Natanblut, Sharon
Subject: Children's Health Protection Advisory Committee

Sharon,

After discussing the outreach plan with EPA senior managers, we would like to engage the Children's Health Protection Advisory Committee (CHPAC) on the draft advice "Fish: What Pregnant Women and Parents Should Know". The CHPAC is a body of external researchers, academicians, health care providers, environmentalists, state and tribal government employees, and members of the public who advise EPA on regulations, research, and communications related to children's health. Members serve voluntarily and the CHPAC meets about two or three times per year to provide specific recommendations to the EPA administrator.

We believe that the third supplemental question posed in the FR noticed is ideally suited for the CHPAC's mission and expertise.

(3) Information upon which to base advice on young children's fish consumption. There have been a number of studies that have examined the effects of both postnatal exposure to mercury as well as postnatal fish consumption by young children, but this research has not been as extensive as the research on prenatal exposures and maternal fish consumption.

We believe the CHPAC would provide valuable feedback and propose directing the CHPAC to respond to this charge during the current comment period. The next CHPAC meeting is scheduled for September 9th and 10th. We could form a workgroup that can begin to draft a response at this meeting. Alternatively, the CHPAC could join the FDA Advisory Committee on Risk Communication to jointly provide advice to the EPA Administrator and FDA Commissioner on both risk communications and fish consumption.

We are currently drafting the agenda for the September meeting and welcome your feedback as we determine if it should include the fish advisory now or table the topic for a joint meeting.

Feel free to contact me if you have questions or concerns.

Thank you,

Khesha Reed

Acting Director

Office of Children's Health Protection

(202) 566-0594

From: Robiou, Grace
Location: DCRoomWest6105AAssateague/DC-EPA-West-OST
Importance: Normal
Subject: Second FDA-EPA Meeting on Fish Advice
Start Date/Time: Tue 4/14/2015 1:00:00 PM
End Date/Time: Tue 4/14/2015 8:00:00 PM

To: Robiou, Grace[Robiou.Grace@epa.gov]
From: Natanblut, Sharon
Sent: Sat 5/16/2015 6:38:55 PM
Subject: Re:

Hi Grace,

Great to hear from you. Yes, the progress continues on all fronts. We hads 2 meetings at FDA and have scheduled two more in the next month or so at which point we hope to have everything drafted and agreed upon by the team.

We definitely miss you. Are you enjoying your new position? How soon can i start trying to get you to come to FDA? Thanks

Sharon

----- Original Message -----
From: Robiou, Grace [mailto:Robiou.Grace@epa.gov]
Sent: Friday, May 15, 2015 06:05 PM
To: Natanblut, Sharon
Subject:

Hi Sharon.

On this Friday, as I close down for the week, I wonder how you think things are doing with the Fish Advice for Mercury. Are we still making progress? I sincerely hope all is well. Regards and have a nice weekend.

Grace Robiou

To: Simons, Andrew[Simons.Andrew@epa.gov]; Kuray, Marilyn[kuray.marilyn@epa.gov]; Wehling, Carrie[Wehling.Carrie@epa.gov]
Cc: Nalven, Heidi[Nalven.Heidi@epa.gov]; Robiou, Grace[Robiou.Grace@epa.gov]
From: Ford, Peter
Sent: Fri 2/20/2015 6:59:50 PM
Subject: FW: Public Docket Rules

Hi Andy, Marilyn, and Carrie,

Is there someone in OGC that Heidi, Grace Robiou from OW (both copied), or I could talk to about rules re federal agencies posting public comments on their public dockets?

See Grace's email below for more info and how FDA is going about this w/r/t joint fish advisories with EPA.

Also, please copy all on response as I will be on international work travel next week, and thus fairly unreachable after today.

Thanks, all.

Peter Z. Ford

U.S. EPA Office of General Counsel

202.564.5593

From: Robiou, Grace
Sent: Friday, February 20, 2015 1:42 PM
To: Ford, Peter; Nalven, Heidi
Subject: Public Docket Rules

Pete/Heidi – Wondering if you can help me with this one…. I need someone to talk to at OGC

about the legal requirements for posting public comments on the docket (be it at EPA or FDA, I am assuming the requirements are the same).

As way of background, we are working with FDA to update the advisory pertaining to how much fish people should eat, based on the concentration of mercury in different fish species. This is what we call the joint FDA-EPA Fish Advisory.

FDA issued a proposed Advisory last year and received public comments. I Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

I wish to talk with someone at OGC to make sure that I know the requirements prior to having a conversation with FDA about this.

Ex. 5 - Deliberative Process

Thanks.

Grace

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Robiou, Grace[Robiou.Grace@epa.gov]
From: Smegal, Deborah
Sent: Tue 2/3/2015 2:49:32 PM
Subject: RE: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Hi Grace,

I remember your name [Ex. 6 - Personal Privacy] intend to include Clark in this effort until his pending retirement this year. I am his current supervisor.

I'm looking forward to contributing and collaborating.

Regards,

Debbie

Deborah Smegal, MPH

Supervisor, Chemical Hazard Assessment Team (CHAT)

Division of Risk Assessment

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Robiou, Grace [mailto:Robiou.Grace@epa.gov]

Sent: Monday, February 02, 2015 11:35 AM
To: Natanblut, Sharon
Cc: Elkin, Ted; Southerland, Elizabeth; Hisel-Mccoy, Sara; Wathen, John; Bigler, Jeff; Larimer, Lisa; Jones, William; Smegal, Deborah
Subject: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Sharon,

Good morning. We do not know each other yet, but I was on the phone with you, Betsy Southerland and others last week when we discussed next steps to finalize the joint FDA-EPA fish advisory.

I work with Jeff Bigler, John Wathen, Lisa Larimer, Sara Hisel-Mccoy and Betsy Southerland. Due to Denise's retirement in December and a pending reorganization of our division, John Wathen is serving as the acting Branch Chief between now and April. Starting in April, I will be the branch chief that covers these programs. Jeff, John and Lisa will be in my branch.

We had a good call last week. I am motivated by the degree of agreement and interest in moving forward together to finalize the fish advisory this year. As a means to facilitate the early stages, I put together the attached one-pager for your review. It describes the general approach and timeline that we discussed last week on the phone. I thought that writing this out would help each of us orient our resources towards this effort.

Last week, we decided that a first good step was to identify the FDA and EPA representatives who would participate in the development of the final Fish Advisory and the response to the public comments fashion (in summary fashion). Here is our team, per Ted's email to Betsy Southerland with the name and contact information for your key folks.

Dr. Williams Jones – FDA/CFSAN (240-402-1422) – William.jones@fda.hhs.gov

Deborah Smegal – FDA/CFSAN (240-402-1818) – Deborah.smegal@fda.hhs.gov

In the past, we have also found Clark Carrington to be a great resource as the keeper of the FDA fish data for mercury. We would like to suggest his inclusion inthe team to work specifically on the binning of the fish for purpose of finalizing the Fish Advisory.

Clark Carrington – FDA/CFSAN (240-402-1947) – clark.carrington@fda.hhs.gov

From EPA, the team would be as follows. We have yet to define roles amongst us, but here is the list with our coordinates.

Jeff Bigler – EPA/Water (202-566-0389) – bigler.jeff@epa.gov

John Wathen – EPA/Water (202-566-0367) – Wathen.john@epa.gov

Lisa Larimer – EPA/Water (202-566-1017) --- Larimer.lisa@epa.gov

Grace Robiou – EPA/Water (202-566-2975) – robiou.grace@epa.gov

EPA proposes to conduct a conference call on Wednesday, February 11, at 1:00pm, for the joint FDA-EPA team to select the sample of substantive public comments that will be reviewed initially to inform the fish advisory. We will be sending out an appointment to reserve that date/time on people's calendars, and to provide a call-in number.

Thank you and we look forward to working with you. You can always reach me at 202-566-2975 if you'd like to chat.

Grace Robiou

EPA/ Water

To: Robiou, Grace[Robiou.Grace@epa.gov]
From: Bigler, Jeff
Sent: Tue 2/3/2015 1:31:03 PM
Subject: Re: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Oh - sorry. My track of time has not been the best.
I do have all 160+ comments. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Jeff

Sent from Jeff Bigler by IPhone

On Feb 3, 2015, at 7:38 AM, "Robiou, Grace" <Robiou.Grace@epa.gov> wrote:

> Jeff,
> Two things. First, the call with FDA is next Wednesday, not this week. I didnt schedule it for this week because you said over the weekend that you expected to be back in the office this Thursday. Second, on the call with FDA you said that you had gained access to all thhe comments. Is that not the case?
>
> Please excuse my typos.
>
> On Feb 3, 2015, at 7:21 AM, "Bigler, Jeff" <Bigler.Jeff@epa.gov> wrote:
>
> > Grace -
> >
> > Ex. 5 - Deliberative Process
> >
> > They are generally very responsive and timely, so I would expect to receive that file today. I'll send it on when I receive it.
> > I should be back in town in time to make the call tomorrow afternoon.
> > Jeff
> >
> > Sent from Jeff Bigler by IPhone
> >
> > On Feb 2, 2015, at 11:37 AM, "Robiou, Grace" <Robiou.Grace@epa.gov> wrote:
> >
> > > Sharon – I should have included in my email that we have secured some funds to have a contractor Ex. 5 - Deliberative Process help us with the response to public comments summary document. The team will decide how a contractor can help, but I thought I would share this piece of good news with you!

Grace

From: Robiou, Grace
Sent: Monday, February 02, 2015 11:35 AM
To: 'Natanblut, Sharon'
Cc: Elkin, Ted; Southerland, Elizabeth; Sara Hisel-McCoy; Wathen, John; Bigler, Jeff; Larimer, Lisa; 'william.jones@fda.hhs.gov'; 'deborah.smegal@fda.hhs.gov'
Subject: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Sharon,

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We had a good call last week. I am motivated by the degree of agreement and interest in moving forward together to finalize the fish advisory this year. As a means to facilitate the early stages, I put together the attached one-pager for your review. It describes the general approach and timeline that we discussed last week on the phone. I thought that writing this out would help each of us orient our resources towards this effort.

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Clark Carrington – FDA/CFSAN (240-402-1947) – clark.carrington@fda.hhs.gov

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John Wathen – EPA/Water (202-566-0367) – Wathen.john@epa.gov

Lisa Larimer – EPA/Water (202-566-1017) --- Larimer.lisa@epa.gov

Grace Robiou – EPA/Water (202-566-2975) – robiou.grace@epa.gov

EPA proposes to conduct a conference call on Wednesday, February 11, at 1:00pm, for the joint FDA-EPA team to select the sample of substantive public comments that will be reviewed initially to inform the fish advisory. We will be sending out an appointment to reserve that date/time on people's calendars, and to provide a call-in number.

Thank you and we look forward to working with you. You can always reach me at 202-566-2975 if you'd like to chat.

Grace Robiou

EPA/ Water

From: Bigler, Jeff
Location: DCRoomWest6105AAssateague/DC-EPA-West-OST
Importance: Normal
Subject: Tentative: Second FDA-EPA Meeting on Fish Advice
Start Date/Time: Tue 4/14/2015 1:00:00 PM
End Date/Time: Tue 4/14/2015 8:00:00 PM

To: Robiou, Grace[Robiou.Grace@epa.gov]
From: Wathen, John
Sent: Tue 1/27/2015 6:12:27 PM
Subject: FW: Documents
Metals_Mercury Levels in Commercial Fish and Shellfish (1990-2010).htm
RCAC 11-04-14.pdf
Ned_Groth_Docket_Comments.docx
Dr. Emily Oken MD MPH_508ED .pdf
fish_advisory_letter_appendices.pdf

From: Wathen, John
Sent: Tuesday, January 27, 2015 10:12 AM
To: Hisel-Mccoy, Sara
Subject: Documents

As requested.

From: Hughes, Denise Y
Location: DC Room West 6105A Assateague/DC-EPA-West-OST
Importance: Normal
Subject: Tentative: Second FDA-EPA Meeting on Fish Advice
Start Date/Time: Tue 4/14/2015 5:00:00 AM
End Date/Time: Tue 4/14/2015 12:00:00 PM

;

To: McRae, Evelyn[McRae.Evelyn@epa.gov]
Cc: Robiou, Grace[Robiou.Grace@epa.gov]
From: Barash, Shari
Sent: Fri 4/10/2015 2:18:04 PM
Subject: NWQSB OD List

Ex. 5 - Deliberative Process

Fish Advice

- We have the second meeting with FDA on Tuesday, 4/14. Lots of work to get ready. We will be ready.

- EPA Comments were submitted on the DGAC docket. Betsy signed the letter.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Wathen, John
Importance: Normal
Subject: Accepted: Second FDA-EPA Meeting on Fish Advice
Start Date/Time: Tue 4/14/2015 1:00:00 PM
End Date/Time: Tue 4/14/2015 8:00:00 PM

From: Bigler, Jeff
Importance: Normal
Subject: Accepted: Second FDA-EPA Meeting on Fish Advice
Start Date/Time: Tue 4/14/2015 1:00:00 PM
End Date/Time: Tue 4/14/2015 8:00:00 PM

To: Jones, William[William.Jones@fda.hhs.gov]
Cc: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Robiou, Grace[Robiou.Grace@epa.gov]
From: Bigler, Jeff
Sent: Fri 2/6/2015 3:10:55 PM
Subject: Re: Blue Sheet Clearance for 2015-76-EPA and FDA Advice About Eating Fish; Closure of the Public Comment Period (Notice)

Thanks Bill -
We are looking forward to the call next week and moving forward with finalizing and implementing the advisory.
Meanwhile, please let me know if there is anything we can do to help with the FRN.
Confirmation and call in info for the call next Wednesday to follow.
Regards,
Jeff

> On Feb 6, 2015, at 9:50 AM, "Jones, William" <William.Jones@fda.hhs.gov> wrote:
>
> Hello Jeff,
>
> It looks like this is soon-to-be hot off the presses, so here is what looks to be the final version of this FR notice. As I understand it, there is interest in getting this out as soon as possible, but a target publication date has not yet been selected. I'll let you know when I hear more about that.
>
> I believe we are in the process of trying to confirm a conference call for next week to begin identifying and coordinating review of the substantive comments.
>
> Talk to you soon,
>
> Bill
>
>
> William R. Jones, Ph.D.
> Lead Senior Advisor and Acting Deputy Director
> Office of Food Safety, HFS-300
> Center for Food Safety and Applied Nutrition, USFDA
> 5100 Paint Branch Parkway
> College Park, MD 20740
>
> _____
> From: Osterman, Rachel
> Sent: Friday, February 06, 2015 9:04 AM
> To: Berry, Gerona; Steadman, Marquita B
> Cc: Jones, William; Chao, Philip; Hall-Wilson, Dashia; Bernard, Susan
> Subject: RE: Blue Sheet Clearance for 2015-76-EPA and FDA Advice About Eating Fish; Closure of the Public Comment Period (Notice)
>
>
> Hi all,
>
> I just Bluesheet cleared the attached in FRDTS. Hopefully, no FRDTS technical problems!
>
> Thanks,
> Rachel

> _____
> From: Berry, Gerona
> Sent: Wednesday, February 04, 2015 10:41 AM
> To: Steadman, Marquita B
> Cc: Jones, William; Chao, Philip; Hall-Wilson, Dashia; Bernard, Susan; Osterman, Rachel
> Subject: Blue Sheet Clearance for 2015-76-EPA and FDA Advice About Eating Fish; Closure of the Public Comment Period (Notice)
> Importance: High
>
>
> Marquita,
>
> Subject document has been referred to OCC for final review and clearance.
>
> << File: 2015-76--Blue Sheet Clearance for 2015-76-EPA and FDA Advice About Eating Fish; Closure of the Public Comment Period (Notice) [In Progress Status].PDF >>
>
> Gerona M. Berry, Program Analyst
> Food and Drug Administration (FDA)
> Office of Foods and Veterinary Medicine (OFVM)
> Center for Food Safety and Applied Nutrition (CFSAN)
> Office of Regulations, Policy, and Social Sciences (ORPSS)
> Room 1C-002, HFS-24
> 5100 Paint Branch Parkway
> College Park, MD 20740-3835
> (240) 402-1719 (Phone)
> (301) 436-2637 (Fax)
> Gerona.Berry@fda.hhs.gov<mailto:Gerona.Berry@fda.hhs.gov>
>
>
>
> <FRDTS___2015-76--Notice_Of_Closure_Of_Comment_Period_Draft_Updated_Fish_Advice_1-26-2015[RO 2-6-15].doc>
> <aims_tempfile_1423230038565670579021627956492 3.pdf>

To: Robiou, Grace[Robiou.Grace@epa.gov]
From: Smegal, Deborah
Sent: Tue 2/3/2015 3:21:00 PM
Subject: RE: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Hi,

Ex. 6 - Personal Privacy

Looking forward to meeting you again soon.

Debbie

Deborah Smegal, MPH

Supervisor, Chemical Hazard Assessment Team (CHAT)

Division of Risk Assessment

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Robiou, Grace [mailto:Robiou.Grace@epa.gov]
Sent: Tuesday, February 03, 2015 10:12 AM
To: Smegal, Deborah
Subject: RE: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Good morning, Debbie.

I recall your name as well. I have a face associated with that name, but I can't recall if we

Ex. 6 - Personal Privacy

Ex. 6 - Personal Privacy In any case, I am looking forward to working together with you and Clark and others on finalizing the Fish Advisory. This is an important effort and I am making it a priority for this year. Appreciate your note – have a great day!

Grace

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Tuesday, February 03, 2015 9:50 AM
To: Robiou, Grace
Subject: RE: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Hi Grace,

Ex. 6 - Personal Privacy

Ex. 6 - Personal Privacy and intend to include Clark in this effort until his pending retirement this year. I am his current supervisor.

I'm looking forward to contributing and collaborating.

Regards,

Debbie

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Division of Risk Assessment

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

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Sent: Monday, February 02, 2015 11:35 AM
To: Natanblut, Sharon
Cc: Elkin, Ted; Southerland, Elizabeth; Hisel-Mccoy, Sara; Wathen, John; Bigler, Jeff; Larimer, Lisa; Jones, William; Smegal, Deborah
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Grace Robiou – EPA/Water (202-566-2975) – robiou.grace@epa.gov

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date/time on people's calendars, and to provide a call-in number.

Thank you and we look forward to working with you. You can always reach me at 202-566-2975 if you'd like to chat.

Grace Robiou

EPA/ Water

To: Sara Hisel-McCoy[Hisel-McCoy.Sara@epa.gov]; Washington, Evelyn[Washington.Evelyn@epa.gov]
Cc: Buffo, Corey[buffo.corey@epa.gov]; Barash, Shari[barash.shari@epa.gov]; Keating, Jim[Keating.Jim@epa.gov]; McRae, Evelyn[mcrae.evelyn@epa.gov]
From: Robiou, Grace
Sent: Fri 3/20/2015 1:33:22 PM
Subject: OD list for National Branch (sending to all since Evelyn is out of the office today)

Reminders for Sara:

•□□□□□□□ We need to schedule a call between Betsy S and Sharon at FDA to discuss two topics: (1) our comments to the Dietary Guidelines Committee Report, and its relationship to our Fish Advice in content and timing, and Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process y when the advice is issued in final form. Could you ask Betsy whether she wants us to arrange for that call via Octavia, or whether she is willing to just call Sharon directly at a time she's available? Thanks.

Ex. 5 - Deliberative Process

Fish Advice

•□□□□□□□ Bunch of things to follow up on based on March 17 meeting, in prep for April 14 meeting.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Sara Hisel-McCoy[Hisel-McCoy.Sara@epa.gov]; Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Robiou, Grace
Sent: Wed 3/18/2015 4:35:40 PM
Subject: FYI - Agreements and Next Steps from March 17th meeting
Agreements and Next Steps from First FDA-EPA Meeting on Final Advice - March 17, 2015.docx

From: Robiou, Grace
Sent: Wednesday, March 18, 2015 12:35 PM
To: 'William.jones@fda.hhs.gov'; 'Carrington, Clark D'; 'Smegal, Deborah'; 'Natanblut, Sharon'; 'Elkin, Ted'
Cc: Bigler, Jeff; Wathen, John; Larimer, Lisa; Naidenko, Olga
Subject: Agreements and Next Steps from March 17th meeting

Colleagues,

Wow, what a great meeting yesterday! As promised, here are my notes from our discussion. I typed them up in the format of "agreements" and "next steps" to facilitate summarizing the outcomes and following up on our to dos. I hope I didn't mischaracterize any agreements, but if I did, please respond to all with your thoughts. This summary isn't perfect but is what I was able to do today with the time alloted, plus it made more sense to get it out to you now, than to spend hours polishing.

Thank you for coming our way yesterday. Our next meeting is April 14th. Same building entrance, although we will reserve a room with more light and adequate technology to allow displaying and editing of the documents in production.

Regards.

Grace Robiou

U.S. EPA/Office of Water

202-566-2975

From: Robiou, Grace
Importance: Normal
Subject: Second FDA-EPA Meeting on Fish Advice
Start Date/Time: Tue 4/14/2015 1:00:00 PM
End Date/Time: Tue 4/14/2015 8:00:00 PM

To: Barash, Shari[Barash.Shari@epa.gov]
From: Robiou, Grace
Sent: Tue 1/12/2016 4:07:10 PM
Subject: Re: FYI Only: Water articles in the Press

Oh wow! I hope you enjoy it! I also hope things are going well with permanent positions. Sara is staying quiet on this and I hope that means good news for you.

On Jan 12, 2016, at 10:28 AM, Barash, Shari <Barash.Shari@epa.gov> wrote:

I would like to touch base, but this week is packed. I'll go look for time the following week or next. **Ex. 6 - Personal Privacy**

Ex. 6 - Personal Privacy

Shari Z. Barash

Acting Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Robiou, Grace
Sent: Tuesday, January 12, 2016 10:27 AM
To: Barash, Shari <Barash.Shari@epa.gov>
Subject: Re: FYI Only: Water articles in the Press

The DGAs are more important, arguably this is now out. Congrats anyway. Would like to touch base soon. This week?

On Jan 12, 2016, at 10:25 AM, Barash, Shari <Barash.Shari@epa.gov> wrote:

Thanks, but not quite. We still didn't get the revised joint advice out, but luckily the

process still influenced the DGAs (so that is a big win).

Shari Z. Barash

Acting Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Robiou, Grace
Sent: Tuesday, January 12, 2016 10:17 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Subject: Fwd: FYI Only: Water articles in the Press

See second article. Congrats!!!

Begin forwarded message:

> **From:** "Bravo, Antonio" <Bravo.Antonio@epa.gov>
> **Date:** January 12, 2016 at 8:11:20 AM EST
> **To:** OW-OWOW-EVERYONE <OWOWOWEVERYONE@epa.gov>
> **Subject: FYI Only: Water articles in the Press**
>
> <image001.gif>
>
> ## Daily News
>
> **States Say Sierra Club Lacks 'Harm' To Justify CWA Rule Suit Intervention**

Posted: January 11, 2016

A coalition of 14 states is fighting Sierra Club's bid to intervene in the states' lawsuit over EPA and the Army Corps of Engineers' joint Clean Water Act (CWA) jurisdiction rule, saying environmentalists lack legal standing to win a role in the litigation because they cannot show more than "speculative" harm from the agencies' regulation.

The legal fight over the rule is ongoing at the same time as lawmakers push legislation that would undo the policy. The House is expected to vote later this week to approve a Congressional Review Act (CRA) resolution to scrap the CWA rule, though President Obama has previously issued veto threats over bills targeting the rule.

EPA and the Corps issued the rule last year in order to resolve confusion about the law's reach following Supreme Court rulings that created competing tests for jurisdiction. But GOP lawmakers and industry groups say the rule is a vast regulatory overreach, while some environmentalists say that the rule is not expansive enough.

The CWA is unclear on whether challenges to the rule must be filed in either federal district or appellate courts, and myriad lawsuits over the rule are pending in both. The U.S. Court of Appeals for the 6th Circuit is crafting a decision on whether it has authority to hear consolidated challenges to the rule, and has stayed implementation of the policy nationwide in the interim. If the court takes the cases, it would moot a slew of district court suits.

But if the 6th Circuit decides that the challenges must be heard first in district court, that would shift attention to the lower court suits -- including the case filed by the 14 states in which Sierra Club wants to intervene.

The states in a Jan. 8 opposition brief urge the U.S. District Court for the District of South Dakota's Southeastern Division to reject intervention.

They argue that Sierra Club's motion is untimely because it was filed nearly six months after the start of the district court case, that it cannot overcome the legal presumption that the federal agencies involved in the suit adequately represent their own interests, and that allowing intervention would unduly delay the litigation.

"Although Plaintiff States do not believe any Sierra Club participation is warranted, if the Court were to allow Sierra Club to participate in this case, it should condition such participation or limit Sierra Club's to participation to *amicus curiae*," says the brief.

Legal Standing

Sierra Club is seeking to intervene in *State of North Dakota, et al., v. EPA, et al.*, on behalf of EPA and the Army Corps of Engineers because it is pushing a broad interpretation of EPA's authority under the law to justify a regulation broader than the one the agency finalized.

But the states in the suit are arguing that Sierra Club cannot establish "Article III" legal standing, which requires that a party must show "injury in fact," a causal link between that injury and the conduct at issue, and that a favorable decision is likely to redress the injury.

The states argue in the brief that Sierra Club's asserted injures, including that its members have "concrete interests in specific water bodies" that injunctive relief for the plaintiff states would strip of protections afforded by the rule, are "speculative" and cannot satisfy the required elements of standing.

"Sierra Club's claims are flawed because none of its members claim a sufficient interest in any waters at issue in this litigation -- those waters located in the Plaintiff States," the states argue. "Merely claiming injury to water bodies they care about is insufficient."

The states cite *Lujan v. National Wildlife Federation*, a 1990 Supreme Court decision in which the court held that "vague allegations of a connection between the environmental group members and lands with which they were concerned were not sufficient to convey standing."

In a footnote in the brief, the states point out that Sierra Club's only indication of a member's connection to a plaintiff state is a Sierra Club member in Minnesota who frequently travels to various wildlife refuges and parks throughout the West and Midwest, including North Dakota.

The states involved in the suit are North Dakota, Alaska, Arizona, Arkansas, Colorado, Idaho, Missouri, Montana, Nebraska, Nevada, New Mexico, South Dakota and Wyoming, with Iowa intervening on behalf of the states.

Disapproval Resolution

Meanwhile, House lawmakers are expected to hold a floor vote this week to approve their version of S.J.Res. 22, a CRA disapproval of the CWA rule that cleared the Senate on Nov. 4 in a 53-44 vote.

The CRA gives Congress 60 days after finalization of an agency rule to block it, but a veto from Obama would require two-thirds of Congress to overcome. The administration previously said that the president's senior advisers would recommend a veto of S.J.Res. 22 back when the Senate was poised to vote on it.

A Nov. 3 Statement of Administration Policy on the CRA resolution said it would "nullify years of work and deny businesses and communities the regulatory certainty needed to invest in projects that rely on clean water. EPA and Army have sought the views of and listened carefully to the public throughout the extensive public engagement process for this rule."

It concluded, "Simply put, S.J. Res. 22 is not an act of good governance. It would sow confusion and invite conflict at a time when our communities and businesses need clarity and certainty around clean water regulation."

While blocking the currently proposed version of the rule could address GOP lawmakers' fears that the rule unlawfully expands the scope of the CWA, it may also bar the Obama administration or a future GOP or Democratic administration from crafting a replacement rule -- despite bipartisan agreement on the need for a definitive rule on the scope of the water law following the high court rulings that created competing tests for jurisdiction.

The law says a rule blocked under the CRA "may not be reissued in substantially the same form, and a new rule that is substantially the same as such a rule may not be issued, unless the reissued or new rule is specifically authorized by a law enacted after the date of the joint resolution disapproving the original rule."

Congress has only used the CRA successfully once before to undo a Clinton-era workplace ergonomics rule, and votes on other EPA rules have failed. For example, senators in a 53-46 vote in June 2012 rejected Sen. James Inhofe's (R-OK) CRA resolution to disapprove EPA's air toxics rule for power plants. -- *Bridget DiCosmo*

Daily News

Federal Dietary Guidelines Encourage Low-Mercury Fish Consumption

Posted: January 11, 2016

Newly released federal dietary guidelines encourage the public to increase its consumption of fish while also for the first time informing that fish species vary in the level of beneficial oils and harmful methylmercury they contain, picking up on draft advice EPA and the Food and Drug Administration (FDA) issued in 2014.

The finalized Dietary Guidelines for Americans (DGA), released Jan. 7, largely sidesteps the controversial advice an advisory panel gave to the Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA), where the advisors urged HHS and USDA to encourage EPA and FDA to reconsider their draft advice on tuna consumption. Tuna is one of the most commonly eaten fish in the U.S.

Instead, the DGA, which supersedes other federal guidance, repeats its 2010 advice, which for the first time set a floor for the amount of fish that Americans should eat on a weekly basis. The latest report reiterates that pregnant women, should eat no less than 8 ounces of fish per week, while not exceeding 12 ounces of fish per week.

New however, is the DGA's recognition that different seafood species contain different levels of methylmercury and varying amounts of beneficial oils. "For the general population, consumption of about 8 ounces per week of a variety of seafood, which provide an average consumption of 250 mg per day of [eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)], is associated with reduced cardiac deaths among individuals with and without

preexisting [cardiovascular disease]," the DGA advises. "Similarly, consumption by women who are pregnant or breastfeeding of at least 8 ounces per week from seafood choices that are sources of DHA is associated with improved infant health outcomes."

The DGA continues by noting that "[w]omen who are pregnant or breastfeeding should consume at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in methylmercury. Obstetricians and pediatricians should provide guidance on how to make healthy food choices that include seafood. Women who are pregnant or breastfeeding and young children should not eat certain types of fish that are high in methylmercury."

The guidelines simplify the 2014 draft advisory from EPA and FDA that sought to balance EPA's traditional concerns that fish can be contaminated with methylmercury, a neurotoxin particularly potent to the developing fetus, with FDA's efforts to encourage women to eat more fish because the lean protein provides beneficial oils like Omega 3s and DHA that boost brain and eye development in the fetus.

The DGA, issued by HHS and USDA, is aimed at broadly advising all Americans on how to eat a healthy diet. It is also used to establish public school lunch menus and which foods are covered as part of federal consumer food subsidy programs.

Dietary Guidelines

Last year the Dietary Guidelines Advisory Committee (DGAC) suggested, based on FDA modeling, that EPA and FDA could increase the amount of albacore tuna that would be safe for these women to eat up to six ounces per week -- advice that horrified environmentalists and public health groups concerned with the amounts of mercury albacore tuna.

At a hearing last March, for example, William Wallace of Consumers Union urged the committee to recommend that EPA and FDA advise "that pregnant women eat no tuna." And in a June statement, several groups argued the DGAC's advice on consumption of albacore tuna would pose risks to children.

Tuna "is by far the largest source of mercury in the American diet, accounting for an estimated 45 percent of all mercury exposure," the

groups said. "Albacore tuna has three times more mercury than light tuna and is therefore an unhealthy choice for pregnant women and children."

By contrast, the tuna industry at the March hearing reiterated the DGAC's advice, and some 29 senators in a letter to the FDA Commissioner Stephen Ostroff last April also encouraged reconsidering the albacore tuna limit, based on the DGAC's report.

The latest DGA does not list any species to avoid, as EPA and FDA do, but it does cite the general principles of those agencies' advice.

For the first time, the DGA lists specific types of seafood to recommend as high in beneficial oils and low in mercury -- not including any kind of tuna. "Seafood choices higher in EPA and DHA but lower in methylmercury are encouraged. Seafood varieties commonly consumed in the United States that are higher in EPA and DHA and lower in methylmercury include salmon, anchovies, herring, shad, sardines, Pacific oysters, trout, and Atlantic and Pacific mackerel (not king mackerel, which is high in methylmercury)."

A source with the Environmental Working Group cautiously praised the new advice. The DGA "gives some idea of the complexity to seafood advice, notably the best things [to eat] . . . it's a good list and it doesn't include tuna," the source says. "Some of it is so basic [what we've asked for and that] EPA and FDA avoided doing."

The source compared the DGA advice favorably to the 2014 draft advisory from EPA and FDA. "Compared to the EPA-FDA advice, this is an improvement," the source said. "It conveys some of the differences in the fish species. It gives a clear list [of recommended fish] and clear advice on numerical [limits]. But, the source adds, the advice is "weak on mercury," noting that it does not provide a list of fish to avoid.

The fishing industry is also touting the new DGA advice, though it also does not mention tuna. "When it comes to seafood the DGA's are clear -- seafood is called out over and over again as a food to encourage," a spokesman for the National Fisheries Institute says. "The DGA's do call for Americans to eat at least 8 [ounces] of fish per week to get the benefits but they also call on pregnant women to eat 8-12 ounces. This is significant because the FDA reports that

currently pregnant women eat only 1.89 [ounces] a week, which means now they're missing out on the benefits of seafood." -- *Maria Hegstad* (mhegstad@iwpnews.com)

Daily News

Report Cites Chemical Spill To Highlight Water Privatization Shortcomings

Posted: January 11, 2016

A think tank that often works with environmental groups is pointing to the failures of a West Virginia drinking water utility to both prevent and respond to the 2014 Elk River chemical spill as an example of the problems with utility privatization, and is calling on the state to return control of drinking water systems to municipalities.

A Jan. 7 report from the Civil Society Institute's Boston Action Research concludes that West Virginia American Water (WVAW), a subsidiary of the American Water Company, was unprepared for the Jan. 9, 2014, incident, where a tank owned by Freedom Industries holding 4-methylcyclohexane methanol ruptured and spilled more than 5,000 gallons of the hazardous substance into the Elk River.

Furthermore, the report says that two years after the spill, the utility remains unprepared for a future emergency -- and its lack of preparedness underscores and highlights shortcomings of all American Water Company holdings as well as privatized water utility models in general.

Environmental groups and some water utilities have long been critical of the privatization of public water systems, most recently in the context of public-private partnerships that have been a key part of the Obama administration and water industry's strategy for mitigating the effects of dwindling federal dollars for billions in water infrastructure needs.

EPA officials, including former *de facto* water chief Ken Kopocis have tried to assure groups that these new initiatives are not intended to replace federal funding mechanisms like state revolving funds.

The recent report concludes that an "infusion of federal taxpayer dollars seems almost inevitable to upgrade the country's water infrastructure."

"In the broader scheme of things, it appears that the competition for public dollars between public and private water companies will increase, as local political and private industry pressure for federal taxpayer dollars mounts," researchers write. "This once again begs the question of why the public should support private water utility profit margins when public ownership and management can accomplish this more efficiently and inexpensively."

Looking specifically at West Virginia, the think tank says "the Freedom Industries chemical spill of January 9, 2014 shows how unprepared the company is to deal with disasters," noting that the spill left about 300,000 customers without water for as many as nine days.

"Customer experience with West Virginia American Water is similar to the experience of other American Water Company customers around the country. Indeed, the inadequate and widely criticized operations of private water companies globally have fomented a movement to remunicipalize privatized water utilities," it adds.

The report finds that WVAW violated "numerous regulations" after the 2014 spill, and has spent too much of its resources on "dividend payments" to investors that could "otherwise be invested in the system."

"The situation with WVAW reflects why privatization of water systems has failed. The failure of privatization is attributed to excessive costs, poor service quality, lack of transparency, workforce cuts, and under-investment, among other things," the report says.

To remedy the system's failings, the group recommends that the state assume public ownership and operation of the Charleston, WV, Regional Water system, arguing that a publicly run system "would emphasize water service, security, and safety over profit margin" and that "transparency would be enhanced." WVAW could do this by potentially negotiating a "takeover" if it were willing to sell, or state municipalities could seek to use eminent domain, the report says. -- *Amanda Palleschi* (apalleschi@iwpnews.com)

<image002.png>	**Everyone's pointing fingers over the water crisis in Flint,...**	**01/12/2016**	**Atlanta Journal-Constitution Online**	**GA** <image003.gif><image0
<image002.png>	**Finger-pointing over toxic tap water in Flint, Michigan**	**01/11/2016**	**CNNMoney.com**	**NY** <image003.gif><image0
<image002.png>	**King: Water crisis in Flint, Mich., is environmental racism**	**01/11/2016**	**Daily News Online**	**NY** <image003.gif><image0
<image002.png>	**Snyder may ask lawmakers for money for Flint crisis**	**01/11/2016**	**Detroit Free Press Online**	**MI** <image003.gif><image0
<image002.png>	**Appeals court upholds large livestock farm regulation**	**01/10/2016**	**Blade, The**	**OH** <image003.gif><image0
<image002.png>	**Stormwater Project To Aid Entire Bay**	**01/10/2016**	**Providence Journal, The**	**RI** <image003.gif><image0
<image002.png>	**TINY LA BELLE PLANS BIG FIGHT AGAINST MORE COAL ASH DUMPING**	**01/10/2016**	**Pittsburgh Post-Gazette**	**PA** <image003.gif><image0

News Headline: Everyone's pointing fingers over the water crisis in Flint,... | <image004.gif><image005.gif>

Outlet Full Name: Atlanta Journal-Constitution Online
News Text: ...and decreased IQs. (Video via NBC) The U.S. Justice Department and the Environmental Protection Agency have stepped in to...

News Headline: Finger-pointing over toxic tap water in Flint, Michigan | <image004.gif><image005.gif>

Outlet Full Name: CNNMoney.com
News Text: ...of Enviromental Quality The U.S. Attorney in Michigan and the federal Environmental Protection Agency are also...

News Headline: King: Water crisis in Flint, Mich., is environmental racism | <image004.gif><image005.gif>

Outlet Full Name: Daily News Online
News Text: The public water in Flint, Mich., is so toxic, so dangerous, that tests confirmed it had over 900 times the EPA limit for lead particles.

News Headline: Snyder may ask lawmakers for money for Flint crisis | <image004.gif><image005.gif>

Outlet Full Name: Detroit Free Press Online
News Text: ...by Snyder, the U.S. Attorney's Office in Detroit is assisting the U.S. Environmental Protection Agency with an investigation....

News Headline: Appeals court upholds large livestock farm regulation | <image005.gif>

Outlet Full Name: Blade, The
News Text: Jan. 11--The U.S. Sixth Circuit Court of Appeals in Cincinnati has upheld a lower court's decision in a case regarding large livestock farms that fall in the concentrated animal feeding operations category, affirming state and federal regulatory agencies cannot be sued for violating federal Clean Water Act permitting procedures they oversee.

The lawsuit was brought in 2014 by Wood County farmers Vickie and Larry Askins of Cygnet shortly after the algae-induced Toledo water crisis in August of that year left nearly 500,000 people with unsafe tap water for three days.

The couple challenged the Ohio General Assembly's controversial 2000 decision -- effective March, 2001 -- to transfer environmental permitting of large livestock farms from the Ohio Environmental Protection Agency to the Ohio Department of Agriculture.

Ohio would become the first state to do that, but bureaucratic delays appear to have cropped up.

The decision has yet to be finalized by the U.S. EPA, according to the judicial panel, although the couple claimed in their lawsuit that the Ohio EPA immediately transferred many of its responsibilities.

"They're doing 90 percent of the NPDES [National Pollutant Discharge Elimination System] permit, but they've never been approved," Ms. Askins said during a recent interview with The Blade.

She said the couple will be speaking to their attorney about whether to attempt to have the case heard by the U.S. Supreme Court. She said it is a strong case dismissed on a technicality.

The Askins and other large livestock farm critics have likened the proposed transfer to the "fox watching the henhouse," because the state's agriculture department also is in the business of promoting large farming operations.

They used the Clean Water Act's citizen lawsuit provision to make their claim.

But in its opinion, the federal appellate court concurred with a ruling by Judge David Katz of U.S. District Court in Toledo. It said it dismissed the claim against the U.S. EPA, the Ohio EPA, and the state agriculture department "for lack of subject matter jurisdiction."

The Askins couple argued in their appeal that a state agency "can run amok and not one citizen in Ohio can stop the resulting chaos" if the Clean Water Act provision cannot be applied.

The federal appeals court said in its ruling, however, that it "must respect the limited nature of

citizen lawsuits under the Clean Water Act."

"If Congress intended the citizen suit to be all encompassing, it would have permitted suit for all violations of the Clean Water Act, rather than specifying limited circumstances," the opinion states.

The judges also concurred that Congress "did not intend to give citizens greater and faster enforcement authority against a state than the U.S. EPA."

The decision was issued weeks after a watchdog group called the Less=More Coalition, in conjunction with the Michigan chapter of the Sierra Club, issued a Nov. 19 report that claimed large livestock farms in the western Lake Erie watershed received more than $16.8 million in direct payments, cost-shares, and other subsidies from the U.S. Department of Agriculture between 2008 and 2015.

The groups have released an interactive online map that shows the locations of 146 large livestock farms within the western Lake Erie watershed, housing a collective 12 million animals that produce more than 630 million gallons of waste annually.

The report claimed millions of taxpayer dollars continued to be disbursed to large livestock farm operators even as concerns about algal toxins rose after the 2014 Toledo water crisis. Manure generated by those large livestock facilities is believed to be one of the algae sources.

Although it is not known how much of that manure spills from lagoons or leaches into waterways after being applied to crop fields as fertilizer, activists contend there are big risks managing that waste and that it must be done well to protect one of the world's largest sources of fresh drinking water.

Contact Tom Henry at: thenry@theblade.com, 419-724-6079, or via Twitter @ecowriterohio.

News Headline: Stormwater Project To Aid Entire Bay | <image005.gif>

Outlet Full Name: Providence Journal, The
News Text: PAWTUCKET

PAWTUCKET \x97 Under gray skies on a recent afternoon, Andrew Silvia stood on the Exchange Street Bridge near City Hall and pointed below to clumps of soapy residue floating on the surface of the Blackstone River.

“It might be coming from an outfall,” Silvia, the city's chief of project development, said as he looked down river. “I'd love to know.”

Silvia doesn't know because Pawtucket has never done a comprehensive assessment of its system of 45 stormwater outfalls that channel runoff carrying contaminants and debris from streets and sidewalks to the city's rivers \x97 and ultimately into Narragansett Bay.

But now with the help of an $83,000 federal grant that will be announced on Monday, Silvia, who is a civil engineer, will oversee the

development of a stormwater master plan that will bring together property ownership data and

computerized mapping. It also will include inspections of catch basins and other parts of the citywide drainage system that, in places, date to the 1800s.

“The project is not going to get us all the way to understanding, but it is a vital step,” Silvia said.

Pawtucket occupies a critical place in the upper reaches of the Narragansett Bay watershed. Not only does the Blackstone River flow through the center of Pawtucket, the Ten Mile River also meanders along the east side of the city and the Moshassuck River cuts through the west side. All three ultimately empty into the Bay.

The work in Pawtucket is one of 11 projects in Rhode Island and Massachusetts that are receiving a total of $815,000 in federal funding through a program administered by the Narragansett Bay Estuary Program and the New England Water Pollution Control Commission. The money is coming from the U.S. Environmental Protection Agency and is being awarded from the two-year-old Southeast New England Program for Coastal Watershed Restoration.

All of the projects aim to restore water quality in the Greater Narragansett Bay watershed. They range from stormwater analysis in Avon, Massachusetts, in the far northeast corner of the watershed to work identifying pollution sources in Little Narragansett Bay in Westerly, in the southwest corner.

And all of them, in one way or another, focus on stormwater runoff, which scientists say is one of the leading threats to the cleanliness and clarity of Narragansett Bay and other waterways in the region.

Runoff from storms can carry nutrients, such as nitrates from lawn fertilizers, into water bodies, leading to algae blooms that can cause low-oxygen conditions that wipe out fish and shellfish. Stormwater can also carry pathogens, like those in pet waste, causing high-bacteria counts that close beaches.

Because of those threats, since the Southeast New England Program was created in 2014 through an effort spearheaded in Congress by U.S. Sen. Jack Reed, it has focused on projects that aim to control and treat stormwater runoff.

And because the watershed is an interconnected system that crosses state and community lines, each project can have wide effects, said Tom Borden, director of the Narragansett Bay Estuary Program.

“The projects are local,” he said, ”but they have implications statewide.

The work in Pawtucket fits that characterization perfectly.

“It's at the top of the system,” said Borden.

Silvia said, “All of these waters are impaired. But to the untrained eye, they look beautiful \x97 which speaks to the challenge we face.”

Along with the federal grant, the city is providing a $28,055 match.

The goal is to come up with a list of 10 priority projects to divert and treat runoff that the city could pursue at a later date. They might include the construction of rain gardens, bioswales, artificial wetlands or other types of so-called green infrastructure.

Mayor Donald Grebien credited Silvia and said the grant “will enable Pawtucket to have a truly robust and effective storm water management program.”

Although the Southeast New England Program provides funding for an area from Westerly to Cape Cod, the grants administered by the Narragansett Bay Estuary Program only cover the western half of the region. Another set of grants \x97 for six projects totaling $800,000 in funding \x97 around Buzzards Bay and on the Cape is also set to be announced on Monday by the Buzzards Bay Estuary Program.

The two estuary programs were tasked with administering the grants in the first two years of the initiative, because they work closely with local communities and understand their environmental challenges, said Borden. The EPA will take over the grant program for the 2016 and 2017 funding years when up to $7 million will be available. A request for proposals was issued last month for the next funding period and the deadline for applications is Jan. 22.

The administration of the grants is changing, he said, but the focus will continue to be on stormwater runoff and its effects.

“Those are the impairments that are a threat to aquatic health,” Borden said.

Silvia, who in a previous job helped develop stormwater plans for universities and private companies, knows that well.

“We who work more closely on this issue see how it ripples through the rest of our lives,” he said.

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(401) 277-7457

On Twitter: @KuffnerAlex

News Headline: TINY LA BELLE PLANS BIG FIGHT AGAINST MORE COAL ASH DUMPING | <image005.gif>

Outlet Full Name: Pittsburgh Post-Gazette
News Text: Only about 250 people live in La Belle, a former coal mining patch on an inside bend of the Monongahela River in Luzerne Township, Fayette County. It's so tiny that it doesn't appear on most maps.

But that hasn't stopped coal-fired power plant operators from dumping thousands of tons of coal ash there over the decades, enough to sicken many of the town's residents, according to Jeremy Ulery, who testified at a state Department of Environmental Protection public hearing last week against a permit that would allow the dumping of much more ash there.

"Our cancer rates are high, people are getting sick, and yet the DEP is considering allowing them to bring more of this toxic stuff into places people can't even find on a map," Mr. Ulery said. "They choose towns like ours because they think we don't matter. But let's see them put this stuff in Pittsburgh or Sewickley. Let's see how that goes over."

Mr. Ulery was one of more than a dozen people to vent frustration and anger in testimony against the five-year permit renewal that would allow Matt Canestrale Contracting Inc. to continue discharging wastewater into the Monongahela River from the abandoned strip mine where coal ash waste has been dumped for decades.

Approval of the National Pollutant Discharge Elimination System permit by the DEP would be a

step toward allowing the Canestrale company to begin accepting coal ash from FirstEnergy's Bruce Mansfield power plant in Shippingport, Beaver County.

The Akron, Ohio-based electric power company has been ordered by the DEP to close its massive, leaky Little Blue Run coal ash impoundment and has floated a plan to barge the 2.5 million tons of ash it generates a year about 100 miles up the Ohio and Monongahela rivers to La Belle and another ash impoundment near its Hatfield's Ferry power plant in Greene County.

John Purcell, the Luzerne Township solicitor, told DEP regulators that township supervisors strongly opposed the permit and would take legal steps to challenge any new importation of ash.

"The coal ash refuse pile already dominates the area along the [Monongahela] river and who knows what it's discharging," Mr. Purcell said. "But the big blue elephant in the room is what will happen in the future if more and more fly ash is brought in. So we're going to fight this. We're not going to stand for it here."

Coal ash is produced when coal is burned, and the dusty residue, as fine as talcum powder, contains varying amounts of arsenic, cadmium, lead, selenium, mercury and other metals. Some of those are toxic, others are known to cause cancer. The ash on the Canestrale property can become airborne when it's windy, blowing into the La Belle residential neighborhoods and the nearby prison, State Correctional Institution Fayette.

"There's tremendous frustration here," said Charles Hunnell, a retired Navy commander and high school economics teacher who lives in Waynesburg. "Why should the kids suffer? Why should we suffer? Why should the prisoners suffer? We're being ignored because it's poor."

According to a federal lawsuit filed in June against the Canestrale company by Public Justice and the Environmental Integrity Project, on behalf of the environmental organization Citizens Coal Council, the La Belle ash dump is discharging aluminum, manganese, sulfates and total dissolved solids above Pennsylvania drinking water standards, and is polluting local streams with levels of sulfate and total dissolved solids at levels that can damage fish and other aquatic life.

"This is as clear a case of environmental injustices as you'll find, particularly in the context of SCI-Fayette," said Patrick Grenter, executive director of the Center for Coalfield Justice. "Not only is the health, livelihood and property of the residents at risk, but also the lives of the 2,000 people incarcerated at the prison and the 800 staff. All of them are being held captive in a toxic environment."

Yma Smith said many of her neighbors and friends are sick or have died from cancer or respiratory problems and called on the DEP to conduct a health study of residents before it approves any permit that would allow more dumping.

"My kids deserve better," Ms. Smith said. "I'm tired of going to funeral homes."

While there's no scientific proof that fly ash or other forms of pollution are causing health problems, Luzerne Township has elevated mortality levels for diseases that have been linked to pollution exposure, according to a 2010 Pittsburgh Post-Gazette ecological study on mortality rates. From 2000 through 2008, Luzerne, which includes La Belle, had heart disease mortality that was 26 percent above the national average, and respiratory disease mortality that was 20 percent higher.

Katherine Ulrey said La Belle is home, but she no longer wants to live there after her 8-year-old son missed 27 days of school last year due to respiratory problems and rashes, and her daughter developed breathing problems. She said the coal ash has polluted the air and made

the water unsafe to drink.

"I'm buying bottled water because the problems are not just in the air but also the water," Ms. Ulrey said. "It's killing all of us and I can't stand it anymore."

Neither the Canestrale company nor FirstEnergy attended the hearing. Canestrale could not be reached for comment. Jennifer Young, a FirstEnergy spokeswoman, said the company is pursuing "multiple options for reuse or disposal of Bruce Mansfield coal combustion residuals," including the La Belle and Hatfield's Ferry facilities.

Ms. Young said the company has received a state permit that will allow it to use the Hatfield's Ferry site and is awaiting the DEP's decision on a beneficial use permit that will allow it to use coal ash on mine reclamation projects, like La Belle.

Joel Koricich, DEP district mining manager, said the hearing, which he attended, was the last in a series of more than half a dozen meetings held on the water discharge permit, which is also under review by the U.S. Environmental Protection Agency.

A decision on whether to grant the water discharge permit renewal and the state coal refuse disposal permit for the La Belle site is months away, he said.

National Pollutant Discharge Elimination System permits, required by federal and state environmental agencies, establish limits on the amount of pollutants that can be discharged by industrial sources into surface waters, such as the Monongahela River, which flows by La Belle.

Antonio Bravo

Office of Wetlands, Oceans & Watersheds

202-566-1976

To: Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Robiou, Grace
Sent: Fri 2/20/2015 8:35:18 PM
Subject: RE: SCHEDULED: Document Number - 2015-03691 Publication Date: 02-24-2015

Yay!

From: Bigler, Jeff
Sent: Friday, February 20, 2015 2:32 PM
To: Wathen, John; Robiou, Grace; Larimer, Lisa
Subject: Fwd: SCHEDULED: Document Number - 2015-03691 Publication Date: 02-24-2015

FYI

Begin forwarded message:

> **From:** "Jones, William" <William.Jones@fda.hhs.gov>
> **Date:** February 20, 2015 at 1:47:59 PM EST
> **To:** "bigler.jeff@epa.gov" <bigler.jeff@epa.gov>
> **Subject: FW: SCHEDULED: Document Number - 2015-03691 Publication Date: 02-24-2015**
>
> FYI
>
> -----Original Message-----
> From: Jedzinak, Daniel
> Sent: Friday, February 20, 2015 1:26 PM
> To: Steadman, Marquita B; Jones, William; Chao, Philip
> Subject: FW: SCHEDULED: Document Number - 2015-03691 Publication Date: 02-24-2015
>
> FYI. We are on track to display the fish notice on Monday, 2/23.
>
> Daniel Jedzinak
> OP/RPMS foods desk (on detail)
> (240) 762 -2309
>
> -----Original Message-----
> From: Shelley, Jason [mailto:jshelley@gpo.gov]
> Sent: Friday, February 20, 2015 12:44 PM
> To: OC Pub Dates
> Subject: SCHEDULED: Document Number - 2015-03691 Publication Date: 02-24-2015

Attention : FDA
Document 2015-03691, Category NOTICES, has been scheduled to publish on 02-24-2015.
This document will be placed on public inspection on 02-23-2015 08:45:00.
The subject of this document is Guidance:.
The Agency Id is Docket No. FDA-2014-N-0595, CFR Title is 0, CFR Part is .
The RIN is NA.
This document has an effective date of .
The comments due date is .
The separate part # for this document is NA.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA-2014-N-0595]
Environmental Protection Agency and Food and Drug Administration Advice about Eating Fish; Closure of the Public Comment Period
AGENCY: Food and Drug Administration, HHS.
ACTION: Notice; closure of the public comment period.
SUMMARY: On June 11, 2014, the Food and Drug Administration (FDA), in coordination with the U.S. Environmental Protection Agency (EPA), (the Agencies), released for public comment draft fish consumption advice entitled "Fish: What Pregnant Women and Parents Should Know." The draft advice would update the Agencies' consumption advice and recommend that women who are pregnant (or might become pregnant) or nursing and anyone who prepares food for young children eat certain amounts and types of fish in order to improve health and developmental outcomes while minimizing risk from methylmercury in fish. The draft advice is consistent with recommendations in the Dietary Guidelines for Americans 2010, which are issued every 5 years by the U.S. Departments of Agriculture and Health and Human Services. FDA and EPA are now announcing the closure of the public comment period.
DATES: The comment period will close on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].
ADDRESSES: Comments may continue to be submitted until [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. FDA will share with EPA all comments submitted to the FDA docket.
FOR FURTHER INFORMATION CONTACT: FDA: William Jones, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1422, email: William.Jones@fda.hhs.gov; EPA: Jeffrey Bigler, MS-4305T, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. N.W., Washington, D.C. 20460, 202-566-0389, email: bigler.jeff@epa.gov.
SUPPLEMENTARY INFORMATION: In the Federal Register of June 11, 2014 (79 FR 33559), FDA, in coordination with EPA, announced the availability of the draft updated fish advice, entitled "Fish: What Pregnant Women and Parents Should Know," for public comment (the notice). The draft advice is available electronically at

http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm393070.htm. The notice stated that the comment period would be open until 30 days after the last transcript became available from either the FDA Risk Communication Advisory Committee (RCAC) meeting to be held on the draft advice or any other public meeting that the Agencies chose to hold on the draft advice (79 FR 33559). The notice also stated that the date for closure of public comment will be published in a future notice in the Federal Register (id.).

[...]

To: Sara Hisel-McCoy[Hisel-McCoy.Sara@epa.gov]; Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Robiou, Grace
Sent: Fri 2/20/2015 8:35:12 PM
Subject: Closure of FDA Comment Period for Fish Advisory

FYI – On Monday 2/23, FDA will post a Federal Register Notice to announce the closing of the public comment period to occur 30 days later.

From: Bigler, Jeff
Sent: Friday, February 20, 2015 2:32 PM
To: Wathen, John; Robiou, Grace; Larimer, Lisa
Subject: Fwd: SCHEDULED: Document Number - 2015-03691 Publication Date: 02-24-2015

FYI

Begin forwarded message:

From: "Jones, William" <William.Jones@fda.hhs.gov>
Date: February 20, 2015 at 1:47:59 PM EST
To: "bigler.jeff@epa.gov" <bigler.jeff@epa.gov>
Subject: FW: SCHEDULED: Document Number - 2015-03691 Publication Date: 02-24-2015

FYI

-----Original Message-----
From: Jedzinak, Daniel
Sent: Friday, February 20, 2015 1:26 PM
To: Steadman, Marquita B; Jones, William; Chao, Philip
Subject: FW: SCHEDULED: Document Number - 2015-03691 Publication Date: 02-24-2015

FYI. We are on track to display the fish notice on Monday, 2/23.

Daniel Jedzinak
OP/RPMS foods desk (on detail)
(240) 762 -2309

-----Original Message-----
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Sent: Friday, February 20, 2015 12:44 PM
To: OC Pub Dates

Subject: SCHEDULED: Document Number - 2015-03691 Publication Date: 02-24-2015

Attention : FDA
Document 2015-03691, Category NOTICES, has been scheduled to publish on 02-24-2015.
This document will be placed on public inspection on 02-23-2015 08:45:00.
The subject of this document is Guidance:.
The Agency Id is Docket No. FDA-2014-N-0595, CFR Title is 0, CFR Part is .
The RIN is NA.
This document has an effective date of .
The comments due date is .
The separate part # for this document is NA.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA-2014-N-0595]
Environmental Protection Agency and Food and Drug Administration Advice about Eating Fish; Closure of the Public Comment Period
AGENCY: Food and Drug Administration, HHS.
ACTION: Notice; closure of the public comment period.
SUMMARY: On June 11, 2014, the Food and Drug Administration (FDA), in coordination with the U.S. Environmental Protection Agency (EPA), (the Agencies), released for public comment draft fish consumption advice entitled "Fish: What Pregnant Women and Parents Should Know." The draft advice would update the Agencies' consumption advice and recommend that women who are pregnant (or might become pregnant) or nursing and anyone who prepares food for young children eat certain amounts and types of fish in order to improve health and developmental outcomes while minimizing risk from methylmercury in fish. The draft advice is consistent with recommendations in the Dietary Guidelines for Americans 2010, which are issued every 5 years by the U.S. Departments of Agriculture and Health and Human Services. FDA and EPA are now announcing the closure of the public comment period.
DATES: The comment period will close on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].
ADDRESSES: Comments may continue to be submitted until [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. FDA will share with EPA all comments submitted to the FDA docket.
FOR FURTHER INFORMATION CONTACT: FDA: William Jones, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1422, email: William.Jones@fda.hhs.gov; EPA: Jeffrey Bigler, MS-4305T, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. N.W., Washington, D.C. 20460, 202-566-0389, email: bigler.jeff@epa.gov.
SUPPLEMENTARY INFORMATION: In the Federal Register of June 11, 2014 (79 FR 33559), FDA, in coordination with EPA, announced the availability of the draft updated

fish advice, entitled "Fish: What Pregnant Women and Parents Should Know," for public comment (the notice). The draft advice is available electronically at http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm393070.htm. The notice stated that the comment period would be open until 30 days after the last transcript became available from either the FDA Risk Communication Advisory Committee (RCAC) meeting to be held on the draft advice or any other public meeting that the Agencies chose to hold on the draft advice (79 FR 33559). The notice also stated that the date for closure of public comment will be published in a future notice in the Federal Register (id.).

[...]

To: Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Robiou, Grace
Sent: Fri 2/6/2015 3:25:54 PM
Subject: RE: Blue Sheet Clearance for 2015-76-EPA and FDA Advice About Eating Fish; Closure of the Public Comment Period (Notice)

Thanks. Will do.

From: Bigler, Jeff
Sent: Friday, February 06, 2015 10:14 AM
To: Robiou, Grace
Subject: Fwd: Blue Sheet Clearance for 2015-76-EPA and FDA Advice About Eating Fish; Closure of the Public Comment Period (Notice)

Grace -

If you would like to confirm with a conf line - here is mine:

Ex. 6 - Personal Privacy

Jeff
Begin forwarded message:

From: "Bigler, Jeff" <Bigler.Jeff@epa.gov>
Date: February 6, 2015 at 10:10:55 AM EST
To: "Jones, William" <William.Jones@fda.hhs.gov>
Cc: "Natanblut, Sharon" <Sharon.Natanblut@fda.hhs.gov>, "Robiou, Grace" <Robiou.Grace@epa.gov>
Subject: Re: Blue Sheet Clearance for 2015-76-EPA and FDA Advice About Eating Fish; Closure of the Public Comment Period (Notice)

Thanks Bill -
We are looking forward to the call next week and moving forward with finalizing and implementing the advisory.
Meanwhile, please let me know if there is anything we can do to help with the FRN.
Confirmation and call in info for the call next Wednesday to follow.
Regards,
Jeff

On Feb 6, 2015, at 9:50 AM, "Jones, William" <William.Jones@fda.hhs.gov> wrote:

Hello Jeff,

It looks like this is soon-to-be hot off the presses, so here is what looks to be the final version of this FR notice. As I understand it, there is interest in getting this out as soon as possible, but a target publication date has not yet been selected. I'll let you know when I hear more about that.

I believe we are in the process of trying to confirm a conference call for next week to begin identifying and coordinating review of the substantive comments.

Talk to you soon,

Bill

William R. Jones, Ph.D.

Lead Senior Advisor and Acting Deputy Director

Office of Food Safety, HFS-300

Center for Food Safety and Applied Nutrition, USFDA

5100 Paint Branch Parkway

College Park, MD 20740

From: Osterman, Rachel

Sent: Friday, February 06, 2015 9:04 AM

To: Berry, Gerona; Steadman, Marquita B

Cc: Jones, William; Chao, Philip; Hall-Wilson, Dashia; Bernard, Susan

Subject: RE: Blue Sheet Clearance for 2015-76-EPA and FDA Advice About Eating Fish; Closure of the Public Comment Period (Notice)

Hi all,

I just Bluesheet cleared the attached in FRDTS. Hopefully, no FRDTS technical problems!

Thanks,

Rachel

From: Berry, Gerona

Sent: Wednesday, February 04, 2015 10:41 AM

To: Steadman, Marquita B

Cc: Jones, William; Chao, Philip; Hall-Wilson, Dashia; Bernard, Susan; Osterman, Rachel

Subject: Blue Sheet Clearance for 2015-76-EPA and FDA Advice About Eating Fish; Closure of the Public Comment Period (Notice)

Importance: High

Marquita,

Subject document has been referred to OCC for final review and clearance.

<< File: 2015-76--Blue Sheet Clearance for 2015-76-EPA and FDA Advice About Eating Fish; Closure of the Public Comment Period (Notice) [In Progress Status].PDF >>

Gerona M. Berry, Program Analyst

Food and Drug Administration (FDA)

Office of Foods and Veterinary Medicine (OFVM)

Center for Food Safety and Applied Nutrition (CFSAN)

Office of Regulations, Policy, and Social Sciences (ORPSS)

Room 1C-002, HFS-24

5100 Paint Branch Parkway

College Park, MD 20740-3835

(240) 402-1719 (Phone)

(301) 436-2637 (Fax)

Gerona.Berry@fda.hhs.gov<mailto:Gerona.Berry@fda.hhs.gov>

<FRDTS___2015-76--

Notice_Of_Closure_Of_Comment_Period_Draft_Updated_Fish_Advice_1-26-2015[RO 2-6-15].doc>

<aims_tempfile_1423230038565670579021627956492 3.pdf>

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Robiou, Grace
Sent: Tue 2/3/2015 5:11:24 PM
Subject: RE: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Ex. 6 - Personal Privacy

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Tuesday, February 03, 2015 10:21 AM
To: Robiou, Grace
Subject: RE: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Hi,

Ex. 6 - Personal Privacy

Looking forward to meeting you again soon.

Debbie

Deborah Smegal, MPH

Supervisor, Chemical Hazard Assessment Team (CHAT)

Division of Risk Assessment

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Robiou, Grace [mailto:Robiou.Grace@epa.gov]
Sent: Tuesday, February 03, 2015 10:12 AM
To: Smegal, Deborah
Subject: RE: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Good morning, Debbie.

I recall your name as well. I have a face associated with that name, but I can't recall if we worked together in Ex. 6 - Personal Privacy

Ex. 6 - Personal Privacy

Grace

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Tuesday, February 03, 2015 9:50 AM
To: Robiou, Grace
Subject: RE: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Hi Grace,

I remember your name Ex. 6 - Personal Privacy

Ex. 6 - Personal Privacy

I'm looking forward to contributing and collaborating.

Regards,

Debbie

Deborah Smegal, MPH

Supervisor, Chemical Hazard Assessment Team (CHAT)

Division of Risk Assessment

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Robiou, Grace [mailto:Robiou.Grace@epa.gov]
Sent: Monday, February 02, 2015 11:35 AM
To: Natanblut, Sharon
Cc: Elkin, Ted; Southerland, Elizabeth; Hisel-Mccoy, Sara; Wathen, John; Bigler, Jeff; Larimer, Lisa; Jones, William; Smegal, Deborah
Subject: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Sharon,

Good morning. We do not know each other yet, but I was on the phone with you, Betsy Southerland and others last week when we discussed next steps to finalize the joint FDA-EPA fish advisory.

I work with Jeff Bigler, John Wathen, Lisa Larimer, Sara Hisel-Mccoy and Betsy Southerland. Due to Denise's retirement in December and a pending reorganization of our division, John Wathen is serving as the acting Branch Chief between now and April. Starting in April, I will be the branch chief that covers these programs. Jeff, John and Lisa will be in my branch.

We had a good call last week. I am motivated by the degree of agreement and interest in moving forward together to finalize the fish advisory this year. As a means to facilitate the early stages, I put together the attached one-pager for your review. It describes the general approach and timeline that we discussed last week on the phone. I thought that writing this out would help each of us orient our resources towards this effort.

Last week, we decided that a first good step was to identify the FDA and EPA representatives who would participate in the development of the final Fish Advisory and the response to the public comments fashion (in summary fashion). Here is our team, per Ted's email to Betsy Southerland with the name and contact information for your key folks.

Dr. Williams Jones – FDA/CFSAN (240-402-1422) – William.jones@fda.hhs.gov

Deborah Smegal – FDA/CFSAN (240-402-1818) – Deborah.smegal@fda.hhs.gov

In the past, we have also found Clark Carrington to be a great resource as the keeper of the FDA fish data for mercury. We would like to suggest his inclusion inthe team to work specifically on the binning of the fish for purpose of finalizing the Fish Advisory.

Clark Carrington – FDA/CFSAN (240-402-1947) – clark.carrington@fda.hhs.gov

From EPA, the team would be as follows. We have yet to define roles amongst us, but here is the list with our coordinates.

Jeff Bigler – EPA/Water (202-566-0389) – bigler.jeff@epa.gov

John Wathen – EPA/Water (202-566-0367) – Wathen.john@epa.gov

Lisa Larimer – EPA/Water (202-566-1017) --- Larimer.lisa@epa.gov

Grace Robiou – EPA/Water (202-566-2975) – robiou.grace@epa.gov

EPA proposes to conduct a conference call on Wednesday, February 11, at 1:00pm, for the joint FDA-EPA team to select the sample of substantive public comments that will be reviewed initially to inform the fish advisory. We will be sending out an appointment to reserve that date/time on people's calendars, and to provide a call-in number.

Thank you and we look forward to working with you. You can always reach me at 202-566-2975 if you'd like to chat.

Grace Robiou

EPA/ Water

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
Cc: Elkin, Ted[Ted.Elkin@fda.hhs.gov]; Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]; Sara Hisel-McCoy[Hisel-McCoy.Sara@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Larimer, Lisa[larimer.lisa@epa.gov]
From: Robiou, Grace
Sent: Mon 2/2/2015 4:37:07 PM
Subject: RE: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Sharon – I should have included in my email that we have secured some funds to have a contractor (Ex. 5 - Deliberative Process help us with the response to public comments summary document. The team will decide how a contractor can help, but I thought I would share this piece of good news with you!

Grace

From: Robiou, Grace
Sent: Monday, February 02, 2015 11:35 AM
To: 'Natanblut, Sharon'
Cc: Elkin, Ted; Southerland, Elizabeth; Sara Hisel-McCoy; Wathen, John; Bigler, Jeff; Larimer, Lisa; 'william.jones@fda.hhs.gov'; 'deborah.smegal@fda.hhs.gov'
Subject: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Sharon,

Good morning. We do not know each other yet, but I was on the phone with you, Betsy Southerland and others last week when we discussed next steps to finalize the joint FDA-EPA fish advisory.

I work with Jeff Bigler, John Wathen, Lisa Larimer, Sara Hisel-Mccoy and Betsy Southerland. Due to Denise's retirement in December and a pending reorganization of our division, John Wathen is serving as the acting Branch Chief between now and April. Starting in April, I will be the branch chief that covers these programs. Jeff, John and Lisa will be in my branch.

We had a good call last week. I am motivated by the degree of agreement and interest in moving

forward together to finalize the fish advisory this year. As a means to facilitate the early stages, I put together the attached one-pager for your review. It describes the general approach and timeline that we discussed last week on the phone. I thought that writing this out would help each of us orient our resources towards this effort.

Last week, we decided that a first good step was to identify the FDA and EPA representatives who would participate in the development of the final Fish Advisory and the response to the public comments fashion (in summary fashion). Here is our team, per Ted's email to Betsy Southerland with the name and contact information for your key folks.

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Deborah Smegal – FDA/CFSAN (240-402-1818) – Deborah.smegal@fda.hhs.gov

In the past, we have also found Clark Carrington to be a great resource as the keeper of the FDA fish data for mercury. We would like to suggest his inclusion inthe team to work specifically on the binning of the fish for purpose of finalizing the Fish Advisory.

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John Wathen – EPA/Water (202-566-0367) – Wathen.john@epa.gov

Lisa Larimer – EPA/Water (202-566-1017) --- Larimer.lisa@epa.gov

Grace Robiou – EPA/Water (202-566-2975) – robiou.grace@epa.gov

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Thank you and we look forward to working with you. You can always reach me at 202-566-2975 if you'd like to chat.

Grace Robiou

EPA/ Water

To: Sara Hisel-McCoy[Hisel-McCoy.Sara@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Robiou, Grace
Sent: Mon 2/2/2015 3:45:54 PM
Subject: FOR QUICK REVIEW: Email to Sharon at FDA
Proposed Approach and Schedule for Finalizing Fish Advisory - Jan 29 2015.docx

SARA – Good morning. I am ready to send out this email to Sharon at FDA. I obtained feedback from Betsy, Jeff, John and Lisa. But before I send it out today, I would like to obtain your blessing as well. Thank you!

Sharon,

Good morning. We do not know each other yet, but I was on the phone with you, Betsy Southerland and others last week when we discussed next steps to finalize the joint FDA-EPA fish advisory.

I work with Jeff Bigler, John Wathen, Lisa Larimer, Sara Hisel-Mccoy and Betsy Southerland. Due to Denise's retirement in December and a pending reorganization of our division, John Wathen is serving as the acting Branch Chief between now and April. Starting in April, I will be the branch chief that covers these programs. Jeff, John and Lisa will be in my branch.

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Deborah Smegal – FDA/CFSAN (240-402-1818) – Deborah.smegal@fda.hhs.gov

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John Wathen – EPA/Water (202-566-0367) – Wathen.john@epa.gov

Lisa Larimer – EPA/Water (202-566-1017) --- Larimer.lisa@epa.gov

Grace Robiou – EPA/Water (202-566-2975) – robiou.grace@epa.gov

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Thank you and we look forward to working with you.

Grace Robiou

EPA/ Water

To: Sara Hisel-McCoy[Hisel-McCoy.Sara@epa.gov]; Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Robiou, Grace
Sent: Thur 1/29/2015 4:49:51 PM
Subject: Quick Feedback Requested: Proposed Approach/Schedule for Finalizing Fish Advisory
Proposed Approach and Schedule for Finalizing Fish Advisory - Jan 29 2015.docx

Sara and Betsy – I'm putting together this attached document to send to Sharon at FDA on Monday. The goal is to reaffirm what we discussed on the phone with FDA earlier this week, and leverage the positive momentum to kick-start the conversations soon. I already obtained and processed comments from John and Lisa, and Jeff told me he would send me his comments on Monday. I'd like to know if you think this is a good idea, or a terrible idea, and if you would be OK with me attempting to establish a relationship with Sharon by sending a final version of this document to her on Monday. Appreciate your feedback. Also, I've secured money for the contractual support. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Robiou, Grace
Sent: Mon 6/1/2015 6:35:33 PM
Subject: RE: Re:

Thank you, Sharon, for your kind words.

-----Original Message-----
From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Friday, May 29, 2015 11:43 AM
To: Robiou, Grace
Subject: RE: Re:

Hi Grace,

I'm so glad you found and responded to my email.

I think Lisa has really stepped up, and we appreciate all she is doing. John too has been great and I think we have a really good group dynamic. Everyone is very respectful of everyone else's views and positions.

You however are a natural leader and I'm delighted to hear that we can continue to stay in touch and that one day you may join us at FDA! Dr. Susan Mayne is the new CFSAN Center director. Ex. 6 - Personal Privacy Ex. 6 - Personal Privacy n the meantime I am glad that you are enjoying your new position.

Be well.
Sharon

-----Original Message-----
From: Robiou, Grace [mailto:Robiou.Grace@epa.gov]
Sent: Friday, May 29, 2015 11:18 AM
To: Natanblut, Sharon
Subject: RE: Re:

Sharon,

Can't believe this email got lost in my inbox!

I am so glad that progress continues. I am so pleased. Ex. 6 - Personal Privacy Ex. 6 - Personal Privacy It does sound like we were able to put enough momentum on the work to have it persist.

I am enjoying my new position. The branch is smaller, the people are very capable, the subject matter is of great interest to me.

Ex. 6 - Personal Privacy

I enjoyed working with you that short period of time and wish to remain in touch. You will find me here if you need my assistance in partnering with EPA or for whatever you want to contact me for.

Good luck with everything.

Best always,
Grace Robiou

-----Original Message-----
From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Saturday, May 16, 2015 2:39 PM
To: Robiou, Grace
Subject: Re:

Hi Grace,

Great to hear from you. Yes, the progress continues on all fronts. We hads 2 meetings at FDA and have scheduled two more in the next month or so at which point we hope to have everything drafted and agreed upon by the team.

Ex. 6 - Personal Privacy

Sharon

----- Original Message -----
From: Robiou, Grace [mailto:Robiou.Grace@epa.gov]
Sent: Friday, May 15, 2015 06:05 PM
To: Natanblut, Sharon
Subject:

Hi Sharon.

On this Friday, as I close down for the week, I wonder how you think things are doing with the Fish Advice for Mercury. Are we still making progress? I sincerely hope all is well. Regards and have a nice weekend.

Grace Robiou

To: Redford, David[Redford.David@epa.gov]; Valente, Betsy[Valente.Betsy@epa.gov]; Weiler, Katherine[Weiler.Katherine@epa.gov]; Rappoli, Brian[Rappoli.Brian@epa.gov]; Benson, Robert[Benson.Robert@epa.gov]; Murphy, Margaret[Murphy.Margaret@epa.gov]; Gross, Ryan[Gross.Ryan@epa.gov]; Maschal, Emma[maschal.emma@epa.gov]; King, Mason[king.mason@epa.gov]; Frungillo, Jaime[Frungillo.Jaime@epa.gov]; Chausson, Juliette[chausson.juliette@epa.gov]; Laabs, Chris[Laabs.Chris@epa.gov]; Fox-Norse, Virginia[Fox-Norse.Virginia@epa.gov]; Watts-Fitzgerald, Kelsey[Watts-Fitzgerald.Kelsey@epa.gov]
From: Robiou, Grace
Sent: Thur 12/15/2016 2:45:40 PM
Subject: Fw: please send OW staff TPs by Friday morning...

Good morning, everyone.

These are the talking points that Joel sent up to Administrator McCarthy last week.

Ex. 5 - Deliberative Process

Regards.

From: Nandi, Romell
Sent: Wednesday, December 14, 2016 2:56 PM
To: OWOW Managers Group; Brown, Sineta
Subject: please send OW staff TPs by Friday morning...

Giving extra time given the holiday party tomorrow.

Below is what Joel sent to the Administrator last week.

Thanks.

Romell

Administrator and company – Here's the OW weekly update. I will be out of the office Monday but Mike will be around and I'm available by phone.

Ex. 5 - Deliberative Process

Actions for Signature: The following 3 packages have been sent forward to OP for your signature:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Upcoming Actions: We anticipate sending forward to OP next week for your signature the following actions:

Ex. 5 - Deliberative Process

Cyanotoxin Ambient Water Quality Criteria for Recreational Waters: On December 13, I anticipate signing and issuing a prepublication FRN for the draft *Human Health Recreational Ambient Water Quality Criteria and/or Swimming Advisories for Microcystins and Cylindrospermopsin – 2016*. The draft document will be available for public comment for 60 days. These draft national recreational water quality criteria and/or swimming advisories are the recommended concentrations of microcystins and cylindrospermopsin in recreational which are protective of human health while swimming or participating in other activities on the water. EPA is proposing these draft values under for states to consider adopting and using for CWA purposes, once approved by EPA. Alternatively, states may choose to use these values as the basis of swimming advisories for public notification purposes at beaches to protect the public.

EPA-USGS Technical Report on Hydrologic Alteration: On December 15, I anticipate signing and issuing a prepublication FRN announcing a final joint EPA/USGS technical report, "Protecting Aquatic Life from Effects of Hydrologic Alteration." The report describes the

Ex. 5 - Deliberative Process

From: Robiou, Grace
Location: FDA (College Park), Room 2E-032 in the CFSAN Wiley building
Importance: Normal
Subject: Declined: 3rd FDA-EPA meeting on fish advice
Start Date/Time: Wed 4/22/2015 12:30:00 PM
End Date/Time: Wed 4/22/2015 4:30:00 PM

I will most likely not attend.

To: Washington, Evelyn[Washington.Evelyn@epa.gov]; Barash, Shari[barash.shari@epa.gov]
From: Robiou, Grace
Sent: Wed 4/15/2015 6:46:36 PM
Subject: FW: Update on revised FDA-EPA fish advice

Evelyn and Shari - Thought you might want to know outcome of mtg with FDA and next steps.

From: Southerland, Elizabeth
Sent: Wednesday, April 15, 2015 1:46 PM
To: Larimer, Lisa
Cc: Robiou, Grace; Wathen, John; Hisel-Mccoy, Sara
Subject: RE: Update on revised FDA-EPA fish advice

What a relief! Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

From: Larimer, Lisa
Sent: Wednesday, April 15, 2015 1:36 PM
To: Southerland, Elizabeth
Cc: Robiou, Grace; Wathen, John; Hisel-Mccoy, Sara
Subject: RE: Update on revised FDA-EPA fish advice

Ex. 5 - Deliberative Process

From: Southerland, Elizabeth
Sent: Wednesday, April 15, 2015 1:24 PM
To: Larimer, Lisa
Cc: Robiou, Grace; Wathen, John; Hisel-Mccoy, Sara

Subject: RE: Update on revised FDA-EPA fish advice

Wonderful news! Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process Would that be a big thing to change?

From: Larimer, Lisa
Sent: Wednesday, April 15, 2015 1:21 PM
To: Southerland, Elizabeth
Cc: Robiou, Grace; Wathen, John; Hisel-Mccoy, Sara
Subject: Update on revised FDA-EPA fish advice

Hi Betsy,

Since Sara is out, I thought I'd give you a quick update on the fish ~~advisory~~ advice. We had a productive face-to-face meeting yesterday, in which the joint group agreed on many issues, including:

Ex. 5 - Deliberative Process

We have another face-to-face meeting scheduled next Wednesday to hammer out the revised Q&As before we lose a bunch of people to travel for a while. In mid-May we will meet again to focus on the response to comments. We have an excellent consolidated table of the comments, and we anticipate filling in our responses will be fairly easy after the work of deciding what the advice and Q&As will say is complete.

I don't want to overpromise, but we may have a revised version of the advice and Q&As ready for management review in May if things continue to go smoothly.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Barash, Shari[barash.shari@epa.gov]
From: Robiou, Grace
Sent: Wed 4/15/2015 2:46:19 PM
Subject: Draft OD List

Had 5 minutes so here's a rough draft for your review!

NWQSB items

- This is Grace's first week in OWOW and last week in OST space. Her computer is being moved on Wednesday.

WQS Regulatory Revisions

Ex. 5 - Deliberative Process

Fish Advice

- Successful second meeting with FDA. Third meeting is 4/22, half day at FDA.

Ex. 5 - Deliberative Process

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Robiou, Grace
Sent: Tue 4/14/2015 12:23:49 PM
Subject: RE: seafood advice

Sharon – Thanks for your kind words. Looking at the attachment, I would say "yes," let us share. I think that based on the agenda, we would be discussing the advice itself right before lunch and then again, right after lunch.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, April 13, 2015 11:49 PM
To: Robiou, Grace
Subject: Re: seafood advice

Oh no, i am so sorry to hear that. **Ex. 6 - Personal Privacy**

Ex. 6 - Personal Privacy

I agree and am totally willing to risk sharing this rough draft. Look forward to seeing you tomorrow.
Sharon

From: Robiou, Grace [mailto:Robiou.Grace@epa.gov]
Sent: Monday, April 13, 2015 08:18 PM
To: Natanblut, Sharon
Subject: Re: seafood advice

Thank you so much Sharon. I opened it and saw it for two minutes. Not enough time to make a sound judgment **Ex. 6 - Personal Privacy**. I promise to look at it before the mtg. My general inclination though is that this group, as a team, is in a really good place. Meaning that I think you can take a risk and present something raw, and it will be well received and worked on together.

I know this is crazy. Crazy! **Ex. 6 - Personal Privacy**

Ex. 6 - Personal Privacy

Ex. 6 - Personal Privacy You will see me there all day, except for lunch hr when I have another commitment, but I will try to let Lisa facilitate more.

I dont know what the past history was, but I have found it a joy to work with you! I hope we cross paths again in the future.

Again, I will look at it tomorrow morning and send you a quick email w more thoughtful input.

Grace

On Apr 13, 2015, at 6:37 PM, Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov> wrote:

> Hi Grace,
>
> The attached document is COMPLETELY NOT READY FOR PRIME TIME!!! I began making some edits to the advice to show how we would now include the chart as well as reorganize the QAs. I then started moving and simplifying things based on our discussion last month, the advisory committee meeting, and some comments. But if we look at it tomorrow, I want to be sure people know that I am completely open to reorganizing it, if the changes are too much I am fine discarding this and starting again.
>
> So, if under these circumstances, you wish to have people take a look at it, that's fine. And if you'd like to hold on it and have us focus on the comments first, that's fine too. Thanks.
>
> Sharon
>
> <Document1 (11).docx>

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Robiou, Grace
Sent: Mon 4/13/2015 6:26:59 PM
Subject: Re: Second FDA-EPA Meeting on Fish Advice

Lisa.
I will need one of the copies you make tomorrow. At home now, no ability to print until meeting time!

Please excuse my typos.

On Apr 13, 2015, at 1:04 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

Hi everyone. Here is the agenda and handouts 1, 2, 5 and 6 for tomorrow's meeting.
[Sharon, if you bring or send the electronic file with the projected mark-ups to the advice, I can project it on the big screen.]

Logistics:
Enter through the EPA West entrance at 1301 Constitution Ave, NW (same one as before) – Federal Triangle metro stop.
Call John Wathen at 202-566-0367 to lead you up.
Meeting will be in 6105A.

Ex. 6 - Personal Privacy

We look forward to seeing you! We have a jam-packed agenda.
Lisa Larimer, P.E.
U.S. Environmental Protection Agency | Washington, DC
Office of Water | Standards and Health Protection Division
☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

-----Original Appointment-----
From: Robiou, Grace
Sent: Tuesday, March 17, 2015 3:31 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Larimer, Lisa; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: Second FDA-EPA Meeting on Fish Advice
When: Tuesday, April 14, 2015 9:00 AM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest6105AAssateague/DC-EPA-West-OST

<Agenda-Fish Advice-041415 FDA-EPA mtg.docx>

<Handout 2 Fish advice chart-041315.xlsx>

<Handout 5 Annotated QA-040715.docx>

<Handout 6 Table of Synthesized Comments-040715.docx>

<Handout 1 Summary of All Public Comments on Advice-040715.docx>

To: Barash, Shari[Barash.Shari@epa.gov]
From: Robiou, Grace
Sent: Mon 4/13/2015 1:20:58 PM
Subject: RE: Priorities

Yes.

Could you ask Agnes or Amber to add you to the OST-MGR group while you're acting? And remove me? Maybe we can do that while at today's 10am.

BTW, I have no staff input for the 10am. I brought it up at a branch meeting over two months ago, and again last week. Then I sent the materials by email last week to see if I would prompt one on one input. Nothing. I visited with Corey this morning and he said he did get some input at generals, so he will bring that for SHPD!

From: Barash, Shari
Sent: Monday, April 13, 2015 9:19 AM
To: Robiou, Grace; Aguirre, Janita
Cc: Vlcan, Manjali; Wilcut, Lars; Leutner, Fred
Subject: RE: Priorities

Grace,

I am also supposed to go to the management meeting, so I will see you there. As I mentioned in person, I got back to Lee and sent him a fresh version to review.

Ex. 6 - Personal Privacy

Shari

Shari Z. Barash

Associate Chief

National Water Quality Standards Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Robiou, Grace
Sent: Monday, April 13, 2015 8:52 AM
To: Aguirre, Janita
Cc: Barash, Shari; Vlcan, Manjali; Wilcut, Lars; Leutner, Fred
Subject: FW: Priorities

Janita – SORRY! I forgot to include you on the list!!!

From: Robiou, Grace
Sent: Monday, April 13, 2015 8:51 AM
To: Barash, Shari; Vlcan, Manjali; Wilcut, Lars; Leutner, Fred
Subject: Priorities

Corey and I need to attend a special OST Managers' Meeting at 10:00 to discuss the Viewpoint Survey. I suggest we have cancel today's Priorities meeting in favor of an email exchange of the main things happening this week. If you would still like to meet, please let me know. Here are my things.

1. I'm out on leave Thursday and Friday. Ex. 6 - Personal Privacy

Ex. 6 - Personal Privacy

3. Tuesday – Grace at all-day meeting with FDA on Fish Advice.

Ex. 5 - Deliberative Process

5. Selenium: Lars, do you need me to talk to Sandy? What is happening this week on Selenium?

To: Wilcut, Lars[Wilcut.Lars@epa.gov]; Barash, Shari[Barash.Shari@epa.gov]; Vlcan, Manjali[Vlcan.Manjali@epa.gov]; Leutner, Fred[Leutner.Fred@epa.gov]
From: Robiou, Grace
Sent: Mon 4/13/2015 1:18:55 PM
Subject: RE: Priorities

Thanks Lars. Super helpful!

-----Original Message-----
From: Wilcut, Lars
Sent: Monday, April 13, 2015 9:02 AM
To: Robiou, Grace; Barash, Shari; Vlcan, Manjali; Leutner, Fred
Subject: RE: Priorities

My priorities this week:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

On selenium, Julianne is cleaning up the what ifs? document, and we're continuing to support the Regional Branch on Kentucky. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

I still have to talk to the OP folks on the implementation materials, so no need to talk to Sandy yet. I'll let you know early this week if I need you to engage her. Thanks!

Lars

From: Robiou, Grace
Sent: Monday, April 13, 2015 8:50 AM
To: Barash, Shari; Vlcan, Manjali; Wilcut, Lars; Leutner, Fred
Subject: Priorities

Corey and I need to attend a special OST Managers' Meeting at 10:00 to discuss the Viewpoint Survey. I suggest we have cancel today's Priorities meeting in favor of an email exchange of the main things happening this week. If you would still like to meet, please let me know. Here are my things.

1. I'm out on leave Thursday and Friday. **Ex. 6 - Personal Privacy**

2. I have an odd schedule today. Mix work and sick leave. **Ex. 6 - Personal Privacy**
Ex. 6 - Personal Privacy

3. Tuesday – Grace at all-day meeting with FDA on Fish Advice.

Ex. 5 - Deliberative Process

5. Selenium: Lars, do you need me to talk to Sandy? What is happening this week on Selenium?

To: McRae, Evelyn[mcrae.evelyn@epa.gov]
From: Robiou, Grace
Sent: Thur 4/9/2015 6:38:19 PM
Subject: FW: Proposed agenda & other info for April 14 FDA-EPA meeting on fish advice
Proposed Agenda-041415 FDA-EPA mtg.docx
Ex. 5 - Deliberative Process for advisory-040715.xlsx
Summary of All Public Comments on Advice 20150407 - Final.docx

Please print the attachments – thank you!

From: Larimer, Lisa
Sent: Thursday, April 09, 2015 1:02 PM
To: Robiou, Grace; William.jones@fda.hhs.gov; 'Carrington, Clark D'; Smegal, Deborah; 'Natanblut, Sharon'; 'Elkin, Ted'
Cc: Bigler, Jeff; Wathen, John; Naidenko, Olga
Subject: Proposed agenda & other info for April 14 FDA-EPA meeting on fish advice

Hi everyone,

We here at EPA are looking forward to meeting with our FDA colleagues next week. In preparation for that, I am sending a proposed agenda (also copied into the email below for ease of responding with suggested changes), the final version of our internal summary of all comments received, and the latest version of the "fish chart" showing Ex. 5 - Deliberative Process (Clark, I will follow up with a more detailed email to you about this.)

Please let me know if you have any suggested additions or changes to the proposed agenda. See you next week!

-Lisa

Proposed Agenda

Second FDA-EPA Meeting on Advice for Mercury Concentrations in Fish

Tuesday, April 14

9:00-9:15 Welcome and Review of Today's Agenda (Grace)

9:15 – 9:30 Verbal Summary of Public Comments that came in at end of Comment period (Westat)
Handout #1: Final Summary of Comments document (not for public release)

9:30 – 10:30 Fish Chart (Lisa)
Handout #2: Chart, Version dated 4/XX/15
Discussion Topics:

Ex. 5 - Deliberative Process

10:30 – 10:45 Break

10:45 – 11:30 Fish Chart, continuation

11:30 – 12:15 Chart Mock ups (Sharon)
Handout #3: Design options

12:15 – 1:15 Lunch

1:15 – 2:45 Revisions to Advice (Sharon)
Handout #4: Red-line strike out

2:45 – 3:00 Break

3:00 – 4:00 Qs and As (Sharon)
Handout #5: Annotated Qs and As Ex. 5 - Deliberative Process

4:00 Next Steps
Handout #6: Table for Response of Comments (for public release)

To: Nandi, Romell[Nandi.Romell@epa.gov]
Cc: Zobrist, Marcus[Zobrist.Marcus@epa.gov]; Smith, Bernicel[Smith.Bernicel@epa.gov]
From: Robiou, Grace
Sent: Tue 7/5/2016 7:20:14 PM
Subject: RE: early deadline for OW weekly report to Administrator items (tomorrow at 3pm)...

I think so. Thanks – then we don't need to include it.

From: Nandi, Romell
Sent: Tuesday, July 05, 2016 3:19 PM
To: Robiou, Grace <Robiou.Grace@epa.gov>
Cc: Zobrist, Marcus <Zobrist.Marcus@epa.gov>; Smith, Bernicel <Smith.Bernicel@epa.gov>
Subject: RE: early deadline for OW weekly report to Administrator items (tomorrow at 3pm)...

Joel had previously informed the Administrator about this in his June 24 report, although he said back then that the FR notice would be signed the week of June 27. But since then I believe he spoke to General Jackson and gave the new date to the Administrator (the date changed to this week, correct?).

From: Robiou, Grace
Sent: Tuesday, July 05, 2016 3:07 PM
To: Nandi, Romell <Nandi.Romell@epa.gov>
Cc: Zobrist, Marcus <Zobrist.Marcus@epa.gov>; Smith, Bernicel <Smith.Bernicel@epa.gov>
Subject: RE: early deadline for OW weekly report to Administrator items (tomorrow at 3pm)...

Romell,

The only item I can think of is the **Ex. 5 - Deliberative Process** Is that worthy of an item?

Ex. 5 - Deliberative Process

Grace

From: Nandi, Romell
Sent: Tuesday, July 05, 2016 2:15 PM
To: OWOW Managers Group <OWOW_Managers_Group@epa.gov>
Subject: early deadline for OW weekly report to Administrator items (tomorrow at 3pm)...
Importance: High

We have an early deadline for any items you think merit Joel mentioning to the Administrator in his weekly email report. **Please send any items to me by 3pm tomorrow**.

Although it is still on the calendar, I think it is likely that July 11 OW Staff meeting will be cancelled (Joel and Ellen are both out, as is Ann), so we probably will not need OW staff TPs this week. But I will let you know if we do wind up needing TPs.

Below is what Joel sent to the Administrator last week:

Romell

Administrator and company – Here's the OW weekly update. Please note that I will be out of the office on annual leave beginning this afternoon and all day tomorrow with little to no email access until July 5. I'll be back in the office on July 6 and 7 before heading out on July 8 for work travel to Singapore. Mike and Ellen will be accessible.

Singapore International Water Week - From July 9 through the 14th, I will lead the EPA delegation to Singapore's International Water Week, which is the premiere international water conference. While in Singapore, I am scheduled to provide opening remarks at the U.S.-Singapore Third Country Training Program on Water Management and the U.S. Pavilion

Opening Ceremony and Ribbon Cutting, participate in panel discussions on urban water management and industrial water solutions/securing water supplies in challenging environments, welcome the Water Trade Mission Delegation for the ASEAN Trade Mission, meet with the U.S. Ambassador, and visit several Singapore Public Utilities Board projects.

LCR Implementation Letters – Next Thursday, we hope to move forward with posting states'

Ex. 5 - Deliberative Process

-

Ex. 5 - Deliberative Process Criteria – Next Thursday I anticipate signing the draft updated aquatic life criteria for **Ex. 5 - Deliberative Process** on which I sent you a separate note last week. Last updated in 1986, the updated criteria will be particularly beneficial for protecting aquatic life in and around coastal harbors and marinas, where antifouling paints and coatings on vessels and marine structures are some of the most commonly identified sources of Ex. 5 - Deliberative Process to the estuarine/marine environment. The draft criteria incorporates a recently-developed saltwater biotic ligand model (BLM) and the latest scientific information for estuarine/marine aquatic organisms. The new criteria are less stringent in many locations, depending on local environmental conditions. We expect this to be noncontroversial, as the feedback we have received from the general public, especially coastal communities and boating associations, the scientific community, and industry stakeholders has been overwhelmingly positive.

Ex. 5 - Deliberative Process

FDA Seafood Advice – This week, Tom and I landed the next steps with FDA for their seafood advice. Ex. 5 - Deliberative Process peer review of the scientific methods underlying this advice.

Meeting with Army - This week I met with General Jackson and Lowry Crook to further

Ex. 5 - Deliberative Process

To: Adm13McCarthy, Gina[Adm13McCarthy.Gina@epa.gov]; Meiburg, Stan[Meiburg.Stan@epa.gov]; Fritz, Matthew[Fritz.Matthew@epa.gov]; Pieh, Luseni[Pieh.Luseni@epa.gov]; Vaught, Laura[Vaught.Laura@epa.gov]; Purchia, Liz[Purchia.Liz@epa.gov]; Distefano, Nichole[DiStefano.Nichole@epa.gov]; Garbow, Avi[Garbow.Avi@epa.gov]; Grantham, Nancy[Grantham.Nancy@epa.gov]; Scaggs, Ben[Scaggs.Ben@epa.gov]; Ragland, Micah[Ragland.Micah@epa.gov]; Rupp, Mark[Rupp.Mark@epa.gov]
Cc: Shapiro, Mike[Shapiro.Mike@epa.gov]; Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Beauvais, Joel
Sent: Sat 12/5/2015 12:55:47 AM
Subject: OW Weekly Update

Administrator and company – Here's the weekly update from OW:

Ex. 5 - Deliberative Process

Fish Advice: Tom and I met this past week with counterparts at FDA to discuss. Nothing to report at this time, but we will be following up and will keep you posted.

Ex. 5 - Deliberative Process

NRDC Informal Notice of Intent to Sue on Perchlorate Drinking Water Standards: Last week, NRDC provided informal notice of their intent to sue the Agency for failure to propose/promulgate a National Primary Drinking Water Regulation (NPDWR) for perchlorate. EPA published a determination to regulate perchlorate under the Safe Drinking Water Act (SDWA) in February 2011. SDWA requires that EPA propose an NPDWR within 24 months of a decision to regulate, and promulgate a final regulation within 18 months of proposal (with an option to extend the deadline 9 months). In accordance with SDWA, EPA requested comment from the SAB in 2012. In 2013 the SAB recommended that the Agency derive a perchlorate MCLG using "physiologically based pharmacokinetic/pharmacodynamic modeling based upon its mode of action rather than the default MCLG approach using the RfD." Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Regional Water Finance Forums: The Water Infrastructure and Resiliency Center hosted the second of a series of regional water finance forums on December 2 in Iselin, New Jersey. These forums bring together communities with drinking water, wastewater, and stormwater project financing needs in an interactive format to hear how communities have made financing decisions with sustainable operations in mind; to network with peers on implementing successful financing strategies; and to interact with experts to discuss local infrastructure financing needs.

Association of National Estuary Programs Meeting: I'm told that your video welcome received a great reception at the National Estuary meeting and that the meeting host, Javier Laureano from the San Juan Bay Estuary Program, sends his warm appreciation for your leadership. Thanks for your support!

To: Adm13McCarthy, Gina[Adm13McCarthy.Gina@epa.gov]; Fritz, Matthew[Fritz.Matthew@epa.gov]; Pieh, Luseni[Pieh.Luseni@epa.gov]; Vaught, Laura[Vaught.Laura@epa.gov]; Distefano, Nichole[DiStefano.Nichole@epa.gov]; Purchia, Liz[Purchia.Liz@epa.gov]; Garbow, Avi[Garbow.Avi@epa.gov]; Ragland, Micah[Ragland.Micah@epa.gov]; Rupp, Mark[Rupp.Mark@epa.gov]; Grantham, Nancy[Grantham.Nancy@epa.gov]; Scaggs, Ben[Scaggs.Ben@epa.gov]
Cc: Shapiro, Mike[Shapiro.Mike@epa.gov]; Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Beauvais, Joel
Sent: Fri 12/18/2015 11:15:09 PM
Subject: OW Weekly Report

Administrator and company – Lots going on but just a few things to report this week. I'll be in the office Monday-Wednesday next week, then out 12/24-12/31 – but available throughout by email or cel.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Fish Advice: We are making some progress with FDA staff on requested changes to and potential peer review of the draft advice; I will be discussing with my FDA counterpart next week. Will look to update you on substance, with Tom Burke, at some point in the near future.

Ex. 5 - Deliberative Process

To: Adm13McCarthy, Gina[Adm13McCarthy.Gina@epa.gov]; Meiburg, Stan[Meiburg.Stan@epa.gov]; Fritz, Matthew[Fritz.Matthew@epa.gov]; Pieh, Luseni[Pieh.Luseni@epa.gov]; Garbow, Avi[Garbow.Avi@epa.gov]; Vaught, Laura[Vaught.Laura@epa.gov]; Purchia, Liz[Purchia.Liz@epa.gov]; Ragland, Micah[Ragland.Micah@epa.gov]; Grantham, Nancy[Grantham.Nancy@epa.gov]; Scaggs, Ben[Scaggs.Ben@epa.gov]
Cc: Shapiro, Mike[Shapiro.Mike@epa.gov]; Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Beauvais, Joel
Sent: Wed 11/25/2015 9:24:15 PM
Subject: OW Weekly Report (early edition)

Administrator and company – An early weekly report from OW this week. Happy Thanksgiving to all of you – hope you have a great holiday!

Ex. 5 - Deliberative Process

Fish Advice: Tom Burke and I will be meeting with FDA Deputy Commissioner Mike Taylor and policy office head Jeremy Sharp next week to discuss next steps. Will keep you posted.

Section 404 "Assumable Waters" Subcommittee Meeting: On 12/1-2, the "Assumable Waters Subcommittee" of the National Advisory Council for Environmental Policy and Technology (NACEPT) will hold its second of 5-6 meetings. Formed in response to requests by the States, the Subcommittee has been charged with providing advice and recommendations on how EPA can clarify how permitting responsibilities would be divided between the state (or tribe) and the Corps, upon state (or tribal) assumption of Section 404 permitting responsibilities. Only 2 states (Michigan and New Jersey) have assumed dredge and fill responsibilities under CWA Section 404(g). The scope of CWR jurisdiction is not within the scope of the charge.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Shapiro, Mike[Shapiro.Mike@epa.gov]
From: Shah, Surabhi
Sent: Fri 11/20/2015 2:49:11 PM
Subject: RE: Urgent, needed by noon Friday - Administrator Report Items for Joel's OW weekly report

Thank you, Mike. Perhaps we can also discuss briefly during our General today.

Best,

Surabhi

Surabhi K. Shah, Director

Urban Waters Program, Office of Water, USEPA

1200 Pennsylvania Avenue NW, Washington, DC 20460

Room 3303 WJC East Building, MC 4101M

T: 202-564-3833 / E: shah.surabhi@epa.gov

From: Shapiro, Mike
Sent: Thursday, November 19, 2015 9:09 PM
To: Shah, Surabhi
Subject: FW: Urgent, needed by noon Friday - Administrator Report Items for Joel's OW weekly report

Michael Shapiro

Deputy Assistant Administrator, Office of Water

US EPA, 4101M

1200 Pennsylvania Ave., NW

Washington, DC 20460

202-564-5700

From: Bethel, Heidi
Sent: Thursday, November 19, 2015 7:36 PM
To: Grevatt, Peter <Grevatt.Peter@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Sawyers, Andrew <Sawyers.Andrew@epa.gov>; Best-Wong, Benita <Best-Wong.Benita@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>; Johnson, Tara <Johnson.Tara@epa.gov>; Nandi, Romell <Nandi.Romell@epa.gov>
Cc: Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>; Shapiro, Mike <Shapiro.Mike@epa.gov>; Peck, Gregory <Peck.Gregory@epa.gov>; Klasen, Matthew <Klasen.Matthew@epa.gov>; Orvin, Chris <Orvin.Chris@epa.gov>; Lousberg, Macara <Lousberg.Macara@epa.gov>; Ruf, Christine <Ruf.Christine@epa.gov>; Shah, Surabhi <Shah.Surabhi@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
Subject: RE: Urgent, neede by noon Friday - Administrator Report Items for Joel's OW weekly report

Joel reminded me to keep in mind that next week is a short week so we may want to think about including items happening the week after Turkey Day also. Thank you.

From: Bethel, Heidi
Sent: Thursday, November 19, 2015 5:10 PM
To: Grevatt, Peter <Grevatt.Peter@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Sawyers, Andrew <Sawyers.Andrew@epa.gov>; Best-Wong, Benita <Best-Wong.Benita@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>; Johnson, Tara <Johnson.Tara@epa.gov>; Nandi, Romell <Nandi.Romell@epa.gov>
Cc: Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>; Shapiro, Mike <Shapiro.Mike@epa.gov>; Peck, Gregory <Peck.Gregory@epa.gov>; Klasen, Matthew <Klasen.Matthew@epa.gov>; Orvin, Chris <Orvin.Chris@epa.gov>; Lousberg, Macara <Lousberg.Macara@epa.gov>; Ruf, Christine <Ruf.Christine@epa.gov>; Shah, Surabhi <Shah.Surabhi@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
Subject: Urgent, neede by noon Friday - Administrator Report Items for Joel's OW weekly report

Good afternoon everyone,

As I discussed this past Tuesday with the SAs, I am requesting your help to develop a short list of timely items to give to Joel to include in his OW weekly update for the Administrator's Office (typically sent on Fridays or the weekend). Below is an example of topics sent last week and are illustrative of the range of items that you could report on, and the brief information and level of detail needed. Joel may also add to the list himself, but we need to give him a draft version to consider. Typically, items are very timely and may include detail not found in other places, some detail may be added by Joel. His e-mails have included both items that happened this week as well as future items in the upcoming week(s).

Apologies for the very fast turn around time today, but could you send any items you think should be included this week to me by 12 noon tomorrow, Friday Nov. 20 (and cc Christine Ruf since I may be working out of the office Friday). I should have more information about a weekly deadline for these items next week. Thanks so much!

Heidi

Deliberative, do not quote or cite

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Fish Advice: My staff and I met with Tom Burke and his folks on this on Friday and made a plan for further engagement with FDA. We will be looking for a brief meeting with you this week to discuss the proposed approach.

Ex. 5 - Deliberative Process

2012 Clean Watersheds Needs Survey: We are tentatively planning to release this report to Congress on November 19. As noted in the update from last week, the survey is a comprehensive assessment of capital needs for clean water infrastructure. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process I am in contact with Nichole to ensure that the timing of release of the report remains appropriate.

Public Meeting on Draft Legionella Control Technologies Document: On November 9, about 200 individuals participated in EPA's public meeting and webinar on the draft document, "Technologies for Legionella Control: Scientific Review". OW staff provided an overview of the draft document as well as an overview of the pesticide registration process under FIFRA. We are accepting written comments to the docket through November 23 and OW staff will be briefing the National Drinking Water Advisory Council on the same topic at their meeting next week, on November 19.

To: Adm13McCarthy, Gina[Adm13McCarthy.Gina@epa.gov]
Cc: Meiburg, Stan[Meiburg.Stan@epa.gov]; Fritz, Matthew[Fritz.Matthew@epa.gov]; Pieh, Luseni[Pieh.Luseni@epa.gov]; Scaggs, Ben[Scaggs.Ben@epa.gov]; Garbow, Avi[Garbow.Avi@epa.gov]; Vaught, Laura[Vaught.Laura@epa.gov]; Distefano, Nichole[DiStefano.Nichole@epa.gov]; Purchia, Liz[Purchia.Liz@epa.gov]; Grantham, Nancy[Grantham.Nancy@epa.gov]; Rupp, Mark[Rupp.Mark@epa.gov]; Ragland, Micah[Ragland.Micah@epa.gov]; Shapiro, Mike[Shapiro.Mike@epa.gov]; Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Beauvais, Joel
Sent: Sat 11/14/2015 9:32:05 PM
Subject: Re: OW Weekly Update

Thanks - that will definitely be part of our conversations and we'll see what we can come up with.

Joel

> On Nov 14, 2015, at 3:57 PM, Adm13McCarthy, Gina <Adm13McCarthy.Gina@epa.gov> wrote:
>
> Big things going on Joel. Just a few comments.
>

Ex. 5 - Deliberative Process

>
> Happy to talk about the fish FDA issue as long as the goal is to get this off our plate soon.
>
> Thanks
>
> Sent from my iPhone
>
>> On Nov 14, 2015, at 3:04 PM, Beauvais, Joel <Beauvais.Joel@epa.gov> wrote:
>>
>> Administrator and company - Here's the OW update for this week. Thanks, again, for coming by the All Hands this past Thursday - you were great, as always, and I think folks really appreciated it.
>>
>> EPA-Army Coordination: **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

>> Fish Advice: My staff and I met with Tom Burke and his folks on this on Friday and made a plan for further engagement with FDA. We will be looking for a brief meeting with you this week to discuss the proposed approach.
>>
>> Cyanotoxins Strategic Plan: **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

>>

>> 2012 Clean Watersheds Needs Survey: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

>>

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To: Adm13McCarthy, Gina[Adm13McCarthy.Gina@epa.gov]; Meiburg, Stan[Meiburg.Stan@epa.gov]; Fritz, Matthew[Fritz.Matthew@epa.gov]; Pieh, Luseni[Pieh.Luseni@epa.gov]; Scaggs, Ben[Scaggs.Ben@epa.gov]; Garbow, Avi[Garbow.Avi@epa.gov]; Vaught, Laura[Vaught.Laura@epa.gov]; Distefano, Nichole[DiStefano.Nichole@epa.gov]; Purchia, Liz[Purchia.Liz@epa.gov]; Grantham, Nancy[Grantham.Nancy@epa.gov]; Rupp, Mark[Rupp.Mark@epa.gov]; Ragland, Micah[Ragland.Micah@epa.gov]
Cc: Shapiro, Mike[Shapiro.Mike@epa.gov]; Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Beauvais, Joel
Sent: Sat 11/14/2015 8:13:46 PM
Subject: RE: OW Weekly Update

Sorry, a couple further items that I forgot to inlude:

Blending: **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

CWR Litigation: **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

From: Beauvais, Joel
Sent: Saturday, November 14, 2015 3:04 PM
To: Adm13McCarthy, Gina; Meiburg, Stan; Fritz, Matthew; Pieh, Luseni; Scaggs, Ben; Garbow, Avi; Vaught, Laura; Distefano, Nichole; Purchia, Liz; Grantham, Nancy; Rupp, Mark; Ragland, Micah
Cc: Shapiro, Mike; Gilinsky, Ellen; Bethel, Heidi
Subject: OW Weekly Update

Administrator and company - Here's the OW update for this week. Thanks, again, for coming by the All Hands this past Thursday - you were great, as always, and I think folks really appreciated it.

Ex. 5 - Deliberative Process

Fish Advice: My staff and I met with Tom Burke and his folks on this on Friday and made a plan for further engagement with FDA. We will be looking for a brief meeting with you this week to discuss the proposed approach.

Cyanotoxins Strategic Plan: **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

2012 Clean Watersheds Needs Survey: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

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To: Bethel, Heidi[Bethel.Heidi@epa.gov]; Lousberg, Macara[Lousberg.Macara@epa.gov]
Cc: Shapiro, Mike[Shapiro.Mike@epa.gov]; Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]
From: Beauvais, Joel
Sent: Fri 11/13/2015 11:56:02 PM
Subject: RE: potential agenda items for the 11/16 OW staff meeting

And here's one more for Monday:

- □□□□□□□□ Internal communications
- □□□□□□□□ Potential management retreat
- □□□□□□□□ Input on Standing Stakeholder Meetings

From: Beauvais, Joel
Sent: Friday, November 13, 2015 5:30 PM
To: Bethel, Heidi <Bethel.Heidi@epa.gov>; Lousberg, Macara <Lousberg.Macara@epa.gov>
Cc: Shapiro, Mike <Shapiro.Mike@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>
Subject: RE: potential agenda items for the 11/16 OW staff meeting

Thanks folks. All these seem like the type of stuff than can be happened in the round-the-table (or not), as opposed to cross-cutting issues on which people specifically want to request agenda time for the group to focus. I don't see much value in identifying these kind of items in advance. We can revisit Monday the point of the polling exercise, or we can just let it go and let people proactively come forward with those types of items if we have them.

Here are items I would like to discuss Monday:

- □□□□□□□□ Internal communications
- □□□□□□□□ Potential management retreat

From: Bethel, Heidi
Sent: Friday, November 13, 2015 4:36 PM
To: Lousberg, Macara <Lousberg.Macara@epa.gov>; Beauvais, Joel <Beauvais.Joel@epa.gov>
Cc: Shapiro, Mike <Shapiro.Mike@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>
Subject: RE: potential agenda items for the 11/16 OW staff meeting

OWOW provided an additional item late today:

OWOW wants a better idea of Joel's expectations for the "OGC led briefing on the interaction of Water Quality Criteria, Standards, Listing, TMDLs and Permitting" (which is currently scheduled for Thursday at 11am – Tom Wall and Jim Havard will attend that briefing for OWOW).

We know that briefing is an OGC lead, but getting that understanding from Joel would probably help Steve, too. And Steve is presumably going to want some input from OWOW and OST.

From: Lousberg, Macara
Sent: Friday, November 13, 2015 3:44 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Cc: Bethel, Heidi <Bethel.Heidi@epa.gov>; Shapiro, Mike <Shapiro.Mike@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>
Subject: potential agenda items for the 11/16 OW staff meeting

Joel – attached and copied in below are the agenda items the program offices teed up for consideration for next Monday's OW staff meeting. The attachment goes with #1 below. I think there's some uncertainty as to whether these types of items are what you have in mind, so I'm sure any feedback will be appreciated. Bringing hard copies over to Crystal.

Macara

Ex. 5 - Deliberative Process

5. Participation on Agriculture Appropriations Subcommittee on Fish Advice – OST

To: Adm13McCarthy, Gina[Adm13McCarthy.Gina@epa.gov]
Cc: Meiburg, Stan[Meiburg.Stan@epa.gov]; Fritz, Matthew[Fritz.Matthew@epa.gov]; Pieh, Luseni[Pieh.Luseni@epa.gov]; Vaught, Laura[Vaught.Laura@epa.gov]; Purchia, Liz[Purchia.Liz@epa.gov]; Distefano, Nichole[DiStefano.Nichole@epa.gov]; Garbow, Avi[Garbow.Avi@epa.gov]; Grantham, Nancy[Grantham.Nancy@epa.gov]; Scaggs, Ben[Scaggs.Ben@epa.gov]; Ragland, Micah[Ragland.Micah@epa.gov]; Rupp, Mark[Rupp.Mark@epa.gov]; Shapiro, Mike[Shapiro.Mike@epa.gov]; Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Beauvais, Joel
Sent: Mon 12/7/2015 11:03:46 AM
Subject: Re: OW Weekly Update

Ex. 5 - Deliberative Process

Joel

On Dec 7, 2015, at 4:45 AM, Adm13McCarthy, Gina <Adm13McCarthy.Gina@epa.gov> wrote:

Thanks Joel. You guys are busy and that's great.

Ex. 5 - Deliberative Process

Thanks

Sent from my iPhone

On Dec 5, 2015, at 1:55 AM, Beauvais, Joel <Beauvais.Joel@epa.gov> wrote:

Administrator and company – Here's the weekly update from OW:

404 Nationwide Permits: **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Fish Advice: Tom and I met this past week with counterparts at FDA to discuss. Nothing to report at this time, but we will be following up and will keep you posted.

Ex. 5 - Deliberative Process

NRDC Informal Notice of Intent to Sue on Perchlorate Drinking Water Standards: Last week, NRDC provided informal notice of their intent to sue the Agency for failure to propose/promulgate a National Primary Drinking Water Regulation (NPDWR) for perchlorate. EPA published a determination to regulate perchlorate under the Safe Drinking Water Act (SDWA) in February 2011. SDWA requires that EPA propose an NPDWR within 24 months of a decision to regulate, and promulgate a final regulation within 18 months of proposal (with an option to extend the deadline 9 months). In accordance with SDWA, EPA requested comment from the SAB in 2012. In 2013 the SAB recommended that the Agency derive a perchlorate MCLG using "physiologically based pharmacokinetic/pharmacodynamic modeling based upon its mode of action rather than the default MCLG approach using the RfD." Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Green Infrastructure Policy for Clean Water State Revolving Fund Issued: On December 10 (tentative), we plan to issue a Green Infrastructure Policy that Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Regional Water Finance Forums: The Water Infrastructure and Resiliency Center hosted the second of a series of regional water finance forums on December 2 in Iselin, New Jersey. These forums bring together communities with drinking water, wastewater, and stormwater project financing needs in an interactive format to hear how communities have made financing decisions with sustainable operations in mind; to network with peers on implementing successful financing strategies; and to interact with experts to discuss local infrastructure financing needs.

Association of National Estuary Programs Meeting: I'm told that your video welcome received a great reception at the National Estuary meeting and that the meeting host, Javier Laureano from the San Juan Bay Estuary Program, sends his warm appreciation for your leadership. Thanks for your support!

Proposed Agenda Items for the 11/16/15 OW Staff Meeting

1. Water Security and Resiliency (see attached fact sheet) – OGWDW
2. Forest Roads Federal Register Notice – OWM
3. Nutrient Recycling Challenge and website launches on Thursday, November 12 – OWM
4. **Ex. 5 - Deliberative Process**
5. Participation on Agriculture Appropriations Subcommittee on Fish Advice – OST

To: Adm13McCarthy, Gina[Adm13McCarthy.Gina@epa.gov]; Meiburg, Stan[Meiburg.Stan@epa.gov]; Fritz, Matthew[Fritz.Matthew@epa.gov]; Pieh, Luseni[Pieh.Luseni@epa.gov]; Distefano, Nichole[DiStefano.Nichole@epa.gov]; Vaught, Laura[Vaught.Laura@epa.gov]; Purchia, Liz[Purchia.Liz@epa.gov]; Garbow, Avi[Garbow.Avi@epa.gov]; Ragland, Micah[Ragland.Micah@epa.gov]
Cc: Shapiro, Mike[Shapiro.Mike@epa.gov]; Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Beauvais, Joel
Sent: Sat 11/7/2015 6:13:11 PM
Subject: OW Weekly Update

Administrator and company – I'm still mid-stream in my transition into OW and am still getting fully up to speed on pending actions and reviewing and adjusting some of the systems for coordination and communication. But there's a lot going on, and I thought it would be good to send a weekly update with some of the key items of which I'm aware. Apologies in advance for the extreme length of this message.

Water Division Directors Meeting: I spent the last three days with OW HQ managers and the Regional Water Division Directors at the WDD meeting in Atlanta, hosted by R4, lead region for water. Day 2 of the meeting was attended by representatives of the key state organizations, including ECOS (Sara Parker Pauley of MO, who is the best), ACWA, ASDWA and the Groundwater Protection Council. The meeting was packed with great presentations and vigorous discussion on a broad range of OW activities and hot topics. It was also a fantastic opportunity for me to start to get to know the regional folks and the state folks, and to get some quality time with many of the OW HQ managers that I already know, as well as some with whom I haven't had as much contact.

Clean Water Rule/Section 404 Coordination:

Ex. 5 - Deliberative Process

•□□□□□□□ I'll also just mention that I had an opportunity to spend a couple hours last week with Lowry Crook (formerly of CEQ and JoEllen's new political deputy), and think that there's a strong appetite and opportunity for coordination there. I'm looking forward to engaging with the team this week on our plan forward on engaging with Army and the Corps, including Gen. Jackson, on the issues discussed above.

Seafood Advisory: Ken, Tom Burke and I met with Stan a couple weeks ago to discuss the path forward on the seafood consumption advice. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process In the meantime, we heard yesterday that the Senate Ag Approps Subcommittee has reached out to FDA requesting a briefing, scheduled for Nov. 16, which FDA has invited EPA to attend. I have alerted Nichole, who is reaching out to FDA leg folks on this.

Gold King Mine Monitoring Plan: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Post-Flint Lead and Copper Rule Guidance Memo: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Peter also did an interview with Michigan Public Radio on Wednesday relating the Flint situation, which I'm told went well.

Upcoming Regs:

• Forest Roads Notice of Opportunity to Provide Info – FR publication 11/10: This Notice, signed by Ken, will publish in the FR on Tuesday 11/10. I sent a separate note with more detailed info on this, but all is in order and this should not attract significant attention.

•□□□□□□□□ NPDES Updates Rule NPRM – Upload for Interagency Review this Week: Ken and OW staff briefed Stan on the NPDES Updates Rule NPRM last Tuesday. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

•□□□□□□□□ SDWA 4th Unregulated Contaminant Monitoring Rule (UCMR 4) NPRM – signature late November: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

•□□□□□□□□ MS4 General Permit Procedures NPRM – Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Other Upcoming Announcements:

•□□□□□□□□ Nutrient Innovation Challenge: On Thursday 11/12, we will announce a National Innovation Challenge for Nutrient Recovery Technologies, a competition to develop affordable technologies to recycle nutrients from livestock waste. The challenge, which involves 4 phases from concept to design to pilot, is being done in partnership with a range of partners, including USDA, pork and dairy producers, and leading universities and technical organizations.

•□□□□□□□□ Clean Watershed Needs Survey: This week or next, we will be announcing the results of the Clean Watershed Needs Survey. This survey is conducted every 4 years as required under CWA sections 205(a) and 516. The report to Congress indicates that the country needs to invest $271 billion to maintain and improve the nation's wastewater infrastructure, including the pipes that carry wastewater to treatment plants, the technology that treats the water, and methods for managing stormwater runoff. We will of course be coordinating with OCIR and

OPA.

•□□□□□□□ Strategic Plan on Cyanotoxins – week of 11/16: Legislation requires EPA to develop and submit to Congress (by Nov. 5) a plan to evaluate harmful cyanotoxins' risk to human health and to recommend feasible treatment options to mitigate adverse health effects, among other tasks. The plan, which I've read and on which Stan has been briefed, summarizes ongoing and future research and other activities of which states and other external stakeholders are aware. The plan has now cleared or will soon clear OMB review. My understanding is that the current target date for release is the week of 11/16 and that the intention is to brief key congressional offices involved in the legislation prior to release; I will provide updates as needed. Again, we will be coordinating with OCIR and OPA.

Onboarding: I wanted to thank you for agreeing to join the OW All Hands meeting this coming Thursday 11/12. This will be my intro to the OW staff and I think it will be a great shot in the arm for the office (and me!) to have you swing by. I have some time on your calendar on Tuesday to talk about transition issues, etc. These next few weeks I expect to be busy balancing drinking from the briefing firehose, managing issues as they come up, getting rolling on review and strengthening of the office's systems on coordination, comms, etc., meeting with RAs and other key internal folks, and doing calls and meetings to get acquainted with key stakeholders, etc.

To: Adm13McCarthy, Gina[Adm13McCarthy.Gina@epa.gov]; Meiburg, Stan[Meiburg.Stan@epa.gov]; Fritz, Matthew[Fritz.Matthew@epa.gov]; Pieh, Luseni[Pieh.Luseni@epa.gov]; Vaught, Laura[Vaught.Laura@epa.gov]; Purchia, Liz[Purchia.Liz@epa.gov]; Distefano, Nichole[DiStefano.Nichole@epa.gov]; Garbow, Avi[Garbow.Avi@epa.gov]; Grantham, Nancy[Grantham.Nancy@epa.gov]; Scaggs, Ben[Scaggs.Ben@epa.gov]; Ragland, Micah[Ragland.Micah@epa.gov]; Rupp, Mark[Rupp.Mark@epa.gov]
Cc: Shapiro, Mike[Shapiro.Mike@epa.gov]; Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Beauvais, Joel
Sent: Sat 12/5/2015 11:39:50 AM
Subject: Re: OW Weekly Update

One additional note: just heard the OMB will likely clear the MS4 Remand Rule NPRM for signature some time early next week.

On Dec 4, 2015, at 7:55 PM, Beauvais, Joel <Beauvais.Joel@epa.gov> wrote:

Administrator and company – Here's the weekly update from OW:

404 Nationwide Permits: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Fish Advice: Tom and I met this past week with counterparts at FDA to discuss. Nothing to report at this time, but we will be following up and will keep you posted.

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Ex. 5 - Deliberative Process

Green Infrastructure Policy for Clean Water State Revolving Fund Issued: On December 10 (tentative), we plan to issue a Green Infrastructure Policy that signals support for increased financing of green infrastructure projects under the Clean Water SRF. The memo indicates that we will work with our partners to continue building support for green infrastructure funding. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

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To: Shapiro, Mike[Shapiro.Mike@epa.gov]
Cc: Penman, Crystal[Penman.Crystal@epa.gov]
From: Sonya Lunder
Sent: Tue 3/15/2016 4:31:12 PM
Subject: Re: Upcoming EWG report on mercury exposures for frequent fish consumers

Thank you!

From: "Shapiro, Mike" <Shapiro.Mike@epa.gov>
Date: Monday, March 14, 2016 at 1:00 PM
To: Sonya Lunder <sonya@ewg.org>
Cc: "Penman, Crystal" <Penman.Crystal@epa.gov>
Subject: RE: Upcoming EWG report on mercury exposures for frequent fish consumers

Ms. Lunder,

Thank you for the information on your forthcoming report. We would like to take you up on your offer to brief us on your findings. Crystal Penman will work with you to arrange an appropriate time.

Mike Shapiro

Michael Shapiro

Deputy Assistant Administrator, Office of Water

US EPA, 4101M

1200 Pennsylvania Ave., NW

Washington, DC 20460

202-564-5700

From: Sonya Lunder [mailto:sonya@ewg.org]
Sent: Friday, March 11, 2016 12:07 PM
To: Shapiro, Mike <Shapiro.Mike@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Lape, Jeff <lape.jeff@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Upcoming EWG report on mercury exposures for frequent fish consumers

Environmental Working Group has long been concerned about the adequacy of EPA and FDA seafood advice for pregnant women. In 2014 we cautioned that women who follow the government recommendations and eat 2 to 3 seafood meals per week during pregnancy could ingest too much mercury.

Next week we are releasing a report that tested hair mercury levels for 254 women who eat 2 or more seafood meals per week. We found that 29% had hair mercury levels >= 1 part per million, roughly equivalent to the reference dose. We found that only 17% of estimated mercury ingestion was from the species presently named in the seafood advice, but that tuna (steaks, sushi, and canned albacore and light) made up 40% of the mercury in our study participants' diets.

We caution that FDA and EPA must expand mercury warnings to ensure that women who follow federal seafood advice achieve the intended benefits during pregnancy. I am attaching the upcoming hair mercury study as well a our 2014 analysis of federal seafood guidelines for your review.

I welcome the opportunity to brief your staff on the findings.

- Sonya Lunder

Sonya Lunder, MPH

Senior Analyst

Environmental Working Group

Washington DC 20009

Sonya@ewg.org

202/939-9129

To: Kopocis, Ken[Kopocis.Ken@epa.gov]; Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Shapiro, Mike[Shapiro.Mike@epa.gov]; Strange, BarbaraA[Strange.BarbaraA@epa.gov]; Penman, Crystal[Penman.Crystal@epa.gov]; Edwards, Crystal[Edwards.Crystal@epa.gov]; Lousberg, Macara[Lousberg.Macara@epa.gov]; Ruf, Christine[Ruf.Christine@epa.gov]; Loop, Travis[Loop.Travis@epa.gov]; Altieri, Sonia[Altieri.Sonia@epa.gov]; Wilson, Elaine[Wilson.Elaine@epa.gov]; Fields, Wanda[Fields.Wanda@epa.gov]; Jones-Coleman, Diane[Jones-Coleman.Diane@epa.gov]
Cc: Goldstein, Elana[Goldstein.Elana@epa.gov]; Klasen, Matthew[Klasen.Matthew@epa.gov]; Greene, Ashley[Greene.Ashley@epa.gov]; Johnson, Tara[Johnson.Tara@epa.gov]; Conerly, Octavia[Conerly.Octavia@epa.gov]; Nandi, Romell[Nandi.Romell@epa.gov]; Erickson, Amber[Erickson.Amber@epa.gov]; WigginsLewis, Miriam[WigginsLewis.Miriam@epa.gov]
From: Bethel, Heidi
Sent: Tue 10/6/2015 10:48:25 AM
Subject: Out of the office today

All,

Ex. 6 - Personal Privacy

Ken,

I have some items for your tribal pre-brief with Stan today and your Ag Stakeholder call tomorrow. We can send the tribal materials up to Matt to get them to Stan once you see them. I will ask Macara to bring materials to you this morning or send to Crystal for printing.

One question: do you want any materials prepared by OST for Stan for the FDA-EPA fish advice meeting on Thursday or will this OW/ORD meeting be discussion only?

Your **Ex. 5 - Deliberative Process** moved to November 5th. I have some more information to share with you about that meeting.

Thanks,

Heidi

Heidi Bethel, Ph.D.

U.S. Environmental Protection Agency

Special Assistant to the Deputy Assistant Administrator

Office of Water

WJC East 3311P

(202) 566-2054

To: Adm13McCarthy, Gina[Adm13McCarthy.Gina@epa.gov]; Meiburg, Stan[Meiburg.Stan@epa.gov]; Fritz, Matthew[Fritz.Matthew@epa.gov]; Pieh, Luseni[Pieh.Luseni@epa.gov]; Vaught, Laura[Vaught.Laura@epa.gov]; Distefano, Nichole[DiStefano.Nichole@epa.gov]; Rupp, Mark[Rupp.Mark@epa.gov]; Benenati, Frank[benenati.frank@epa.gov]; Grantham, Nancy[Grantham.Nancy@epa.gov]; Ragland, Micah[Ragland.Micah@epa.gov]; Flynn, Mike[Flynn.Mike@epa.gov]; Garbow, Avi[Garbow.Avi@epa.gov]
Cc: Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Shapiro, Mike[Shapiro.Mike@epa.gov]; Campbell, Ann[Campbell.Ann@epa.gov]; Gude, Karen[Gude.Karen@epa.gov]
From: Beauvais, Joel
Sent: Thur 6/30/2016 5:26:22 PM
Subject: OW Weekly Update

Administrator and company – Here's the OW weekly update. Please note that I will be out of the office on annual leave beginning this afternoon and all day tomorrow with little to no email access until July 5. I'll be back in the office on July 6 and 7 before heading out on July 8 for work travel to Singapore. Mike and Ellen will be accessible.

Singapore International Water Week - From July 9 through the 14th, I will lead the EPA delegation to Singapore's International Water Week, which is the premiere international water conference. While in Singapore, I am scheduled to provide opening remarks at the U.S.-Singapore Third Country Training Program on Water Management and the U.S. Pavilion Opening Ceremony and Ribbon Cutting, participate in panel discussions on urban water management and industrial water solutions/securing water supplies in challenging environments, welcome the Water Trade Mission Delegation for the ASEAN Trade Mission, meet with the U.S. Ambassador, and visit several Singapore Public Utilities Board projects.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

EOP Meeting on DW Engagement – Last week we had a good call with the CEQ, OMB, and OSTP folks to provide an update on the stakeholder meetings held a few weeks ago on drinking water and the upcoming July 19 convening with stakeholders to discuss funding and financing for drinking water and wastewater infrastructure for communities in need. We are making progress on an outline and timeline for the drinking water action plan and hope to brief you in a few weeks when Peter and I are back from Singapore.

FDA Seafood Advice – This week, Tom and I landed the next steps with FDA for their seafood advice. Ex. 5 - Deliberative Process
peer review of the scientific methods underlying this advice.

Meeting with Army - This week I met with General Jackson and Lowry Crook to further discussion on Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

National Drought Resilience Partnership - On Monday I attended the first meeting of the NDRP Principals Committee, chaired by DOC/NOAA and USDA. The purpose of the meeting was to familiarize the principals about the Presidential Memo on Drought and its requirements, to review the Charter of the NDRP to gain an understanding of the roles of responsibilities of each agency, and to receive a progress update on each of the six drought related goals under the Charter. OW has been involved from the start in the NDRP, and its goals reflect the work EPA is doing on drought response and climate resilience. EPA chairs two of the six goals team, focusing on market-based approaches for infrastructure and efficiency, and innovative water use, efficiency and technology. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Beauvais, Joel[Beauvais.Joel@epa.gov]
Cc: Meiburg, Stan[Meiburg.Stan@epa.gov]; Fritz, Matthew[Fritz.Matthew@epa.gov]; Vaught, Laura[Vaught.Laura@epa.gov]; Garbow, Avi[Garbow.Avi@epa.gov]; Benenati, Frank[benenati.frank@epa.gov]; Grantham, Nancy[Grantham.Nancy@epa.gov]; Distefano, Nichole[DiStefano.Nichole@epa.gov]; Rupp, Mark[Rupp.Mark@epa.gov]; Ragland, Micah[Ragland.Micah@epa.gov]; Pieh, Luseni[Pieh.Luseni@epa.gov]; Flynn, Mike[Flynn.Mike@epa.gov]; Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Shapiro, Mike[Shapiro.Mike@epa.gov]; Campbell, Ann[Campbell.Ann@epa.gov]; Gude, Karen[Gude.Karen@epa.gov]
From: Adm13McCarthy, Gina
Sent: Fri 6/24/2016 9:28:34 PM
Subject: Re: OW Weekly Update

Thanks for the work on my little LIS. Much appreciated.

Sent from my iPhone

On Jun 24, 2016, at 1:58 PM, Beauvais, Joel <Beauvais.Joel@epa.gov> wrote:

Administrator and company – Here's the OW weekly update. Please note that I will be out of the office on annual leave Thursday afternoon and all day Friday with little to no email access until July 5. Ellen and Mike will be accessible. Had a good session this morning with the Mayors Water Council at the US Conference of Mayors meeting in Indy and will be working with Mark to pursue follow up engagement with them on drinking water issues.

LCR Implementation Follow-up Letters: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Long Island Sound Dredging Rule: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

FDA Seafood Advice: Ex. 5 - Deliberative Process we heard back from FDA that they are interested in moving forward with peer review of the draft advice. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Will keep you updated on developments.

Puerto Rico SRF: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Water Quality Standards for Selenium in the San Francisco Bay and Delta: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Selenium Ambient Water Quality Criteria for the Protection of Aquatic Life: On Friday, I anticipate signing the final updated aquatic life water quality criterion for selenium in freshwater. The final criterion takes into account selenium bioaccumulation in aquatic food webs and is expressed in terms of two fish tissue elements and two water column elements. EPA will recommend that states include all four elements in their water quality standards in a hierarchal fashion reflecting the primacy of fish tissue elements over water column elements. In the development of this criterion, EPA partnered with multiple offices within the agency, USGS, and several Regions. This document underwent two rounds of public comment and external peer review. As I mentioned in my earlier email on this and discussed with Stan and Laura in our briefing last week, OW, ORD, and the Regions are working to produce a set of technical support documents designed to assist states and other stakeholders in implementation of the final selenium criterion. We plan to release these implementation documents later in 2016 and will conduct additional outreach at that time.

Ex. 5 - Deliberative Process

MOU for Permitting Offshore Aquaculture Activities in Federal Waters of the Gulf of Mexico: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Shapiro, Mike[Shapiro.Mike@epa.gov]
From: Gilinsky, Ellen
Sent: Tue 6/21/2016 1:27:17 AM
Subject: Re: Final Seafood Advice

Let's hope so

Sent from my iPhone

On Jun 20, 2016, at 8:41 PM, Shapiro, Mike <Shapiro.Mike@epa.gov> wrote:

> Ellen,
>
> Thanks, seems like things are beginning to move.
>
> Mike
>
> Sent from my iPhone
>
> On Jun 20, 2016, at 4:00 PM, Gilinsky, Ellen <Gilinsky.Ellen@epa.gov> wrote:
>
> > Mike a lot is going on re the seafood advice re mercury.....see this and other emails I forwarded
> >
> > **Ellen Gilinsky**
> >
> > Ellen Gilinsky, Ph.D.
> >
> > Senior Policy Advisor
> >
> > Office of Water
> >
> > 1200 Pennsylvania Ave, NW
> >
> > Room 3219B EPA East, MC 4101M
> >
> > Washington, DC 20460

Phone: 202-564-2549

Cell: 202-236-6882

Email: Gilinsky.ellen@epa.gov

From: Southerland, Elizabeth
Sent: Monday, June 20, 2016 1:51 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Final Seafood Advice

We reviewed the revised draft charge from FDA (and corresponding email from Jeremy) and compared it to the version we sent to them in January (both versions are attached).

Overall we do not have any issues with FDA's changes to the charge to the peer reviewers.

For your information, we found the following changes:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Begin forwarded message:

From: "Beauvais, Joel" <Beauvais.Joel@epa.gov>
Date: June 17, 2016 at 12:33:14 PM EDT
To: "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Cc: "Campbell, Ann" <Campbell.Ann@epa.gov>
Subject: FW: Final Seafood Advice

Hi, Betsy – Can I get your input on this in advance of engaging with Tom B?

Joel

From: Sharp, Jeremy [mailto:Jeremy.Sharp@fda.hhs.gov]
Sent: Friday, June 17, 2016 12:09 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Subject: Final Seafood Advice

Joel, I apologize for the long delay in my engagement of you on this. In our in-person meeting about EPA's concerns and proposed changes to the FDA-EPA fish advice, you outlined 3 general areas of concern. We are most anxious to move forward to finalize the advice, and in the time since our meeting have worked to address and respond to your requests as noted below.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process We look forward to hearing from you as soon as possible.

Jeremy Sharp

Deputy Commissioner

Policy, Planning, Legislation, and Analysis

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, Maryland 20993

301-796-8770

<Revised Peer Review Charge_4-14-16_final.docx>

<PeerReviewChargeQsDRAFT_01 11 16.docx>

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
Cc: Campbell, Ann[Campbell.Ann@epa.gov]; Shapiro, Mike[Shapiro.Mike@epa.gov]; Loop, Travis[Loop.Travis@epa.gov]
From: Beauvais, Joel
Sent: Tue 1/10/2017 4:36:37 PM
Subject: RE: Seafood advice

Thx. I just spoke to Jeremy and they are good to go with rolling this out next Tuesday or Wednesday. They are going to reach out on comms.

Joel

-----Original Message-----
From: Southerland, Elizabeth
Sent: Tuesday, January 10, 2017 11:32 AM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>
Subject: RE: Seafood advice

Our contacts at FDA all believe they are in the process of releasing on Jan 16. I will email Sharon Natanblut right now and see what is going on. They were working with Travis et al to complete the communication materials.

-----Original Message-----
From: Beauvais, Joel
Sent: Tuesday, January 10, 2017 9:06 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>
Subject: Seafood advice

Where are we on this? I never heard back from Jeremy at FDA.

To: Beauvais, Joel[Beauvais.Joel@epa.gov]
Cc: Campbell, Ann[Campbell.Ann@epa.gov]; Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Shapiro, Mike[Shapiro.Mike@epa.gov]
From: Loop, Travis
Sent: Fri 1/6/2017 3:40:18 AM
Subject: Re: Further Update re: Seafood Advice

From the comms end we haven't seen their press release and roll out plan yet. I am, however, connected with their lead comms person.

Travis Loop
Communications Director for Water
U.S. Environmental Protection Agency
Phone: 202.870.6922
Follow us on Twitter @EPAwater

On Jan 5, 2017, at 9:27 PM, Beauvais, Joel <Beauvais.Joel@epa.gov> wrote:

> OK, Jeremy from FDA asked for a call tomorrow so I have asked Crystal to set that up. T Ex. 5 - Deliberative Process
> **Ex. 5 - Deliberative Process**
>
> On Jan 5, 2017, at 6:42 PM, Campbell, Ann <Campbell.Ann@epa.gov> wrote:
>
> > Joel, I'm told Nothing substantive has changed since your last briefing. HHS requested minor wording changes to the Q&A [redacted] Ex. 5 - Deliberative Process
> > **Ex. 5 - Deliberative Process** The FRN is attached for your review.
> >
> > Where things stand currently: FDA and EPA have been working collaboratively on the materials for the fish advice. Folks are still working on redesigned web pages, scripts for the media call and outreach to stakeholder groups, but the documents associated with the advice (e.g., chart with the fish types and recommended consumption frequency, Q&A, *Federal Register* notice) are ready to go. The web pages could be ready early next week; Travis Loop would know when the communication materials could be ready.
> >
> > <2015-646_fish advice NOA. 10.31.2016 Final Version.docx>

To: Beauvais, Joel[Beauvais.Joel@epa.gov]
Cc: Loop, Travis[Loop.Travis@epa.gov]; Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Shapiro, Mike[Shapiro.Mike@epa.gov]
From: Campbell, Ann
Sent: Thur 1/5/2017 10:16:21 PM
Subject: UPDATE: Seafood Advice

Joel, you should expect a call from Jeremy. They want our commitment to get this out in the next 10 days. I've asked OST to provide a write-up as to where we are substantively. When I have it, I'll pass it along. Let me know if you need anything else.

From: Southerland, Elizabeth
Sent: Thursday, January 05, 2017 4:17 PM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: RE: Seafood Advice

Just got a message from Sharon Natanblut who is on vacation now. She left me a voice message that Jeremy Sharp will be calling Joel today and ask for a final reassurance that EPA is excited about getting the advice out in the next 10 days!!! According to my calculation, that would mean Jan. 16. Of course, Joel knows we have all been lighting the expensive $2 candles praying for release of the advice asap. Looks like all that fire power has worked……

From: Hisel-Mccoy, Sara
Sent: Thursday, January 05, 2017 12:31 PM
To: Campbell, Ann <Campbell.Ann@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Subject: RE: Seafood Advice

Ann,

It is feeling surreal. So, our POC at FDA, Sharon Natanblut has a meeting with her Deputy Commissioner for Policy this afternoon to discuss fish advice. We will know more after we hear about how that discussion goes. We have no word on OMB discussions.

From: Campbell, Ann
Sent: Thursday, January 05, 2017 12:15 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Subject: Seafood Advice

Any word on where this stands?

To: Adm13McCarthy, Gina[Adm13McCarthy.Gina@epa.gov]; Meiburg, Stan[Meiburg.Stan@epa.gov]; Fritz, Matthew[Fritz.Matthew@epa.gov]; Vaught, Laura[Vaught.Laura@epa.gov]; Distefano, Nichole[DiStefano.Nichole@epa.gov]; Rupp, Mark[Rupp.Mark@epa.gov]; Benenati, Frank[benenati.frank@epa.gov]; Grantham, Nancy[Grantham.Nancy@epa.gov]; Garbow, Avi[Garbow.Avi@epa.gov]; Ragland, Micah[Ragland.Micah@epa.gov]; Pieh, Luseni[Pieh.Luseni@epa.gov]; Flynn, Mike[Flynn.Mike@epa.gov]
Cc: Gilinsky, Ellen[Gilinsky.Ellen@epa.gov]; Shapiro, Mike[Shapiro.Mike@epa.gov]; Campbell, Ann[Campbell.Ann@epa.gov]; Gude, Karen[Gude.Karen@epa.gov]
From: Beauvais, Joel
Sent: Sun 12/11/2016 11:09:31 PM
Subject: OW Weekly Report

Administrator and company – Here's the OW weekly update. I will be out of the office Monday but Mike will be around and I'm available by phone.

Lead Modeling: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Seafood Advice: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Actions for Signature: The following 3 packages have been sent forward to OP for your signature:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Upcoming Actions: We anticipate sending forward to OP next week for your signature the following actions:

· Third Six Year Review: We expect to submit the Third Six- Year Review of Existing National Primary Drinking Water Regulations (NPDWR) Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

· Regulations Implementing Section 1417 of the Safe Drinking Water Act: Prohibition on Use of Lead Pipes, Solder, and Flux: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

CWA Jurisdictional Determinations Website: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Cyanotoxin Ambient Water Quality Criteria for Recreational Waters: On December 13, I anticipate signing and issuing a prepublication FRN for the draft *Human Health Recreational Ambient Water Quality Criteria and/or Swimming Advisories for Microcystins and Cylindrospermopsin – 2016*. The draft document will be available for public comment for 60 days. These draft national recreational water quality criteria and/or swimming advisories are the recommended concentrations of microcystins and cylindrospermopsin in recreational which are protective of human health while swimming or participating in other activities on the water. EPA is proposing these draft values under for states to consider adopting and using for CWA purposes, once approved by EPA. Alternatively, states may choose to use these values as the basis of swimming advisories for public notification purposes at beaches to protect the public.

EPA-USGS Technical Report on Hydrologic Alteration: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Draft Recommended Field-based Method for Developing Aquatic Life Criteria for Specific Conductivity: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Release of Updated Guidance for Conducting Fish Consumption Surveys: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ocean Acidification Petition Response: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Sonya Lunder[sonya@ewg.org]
Cc: Crystal Penman[penman.crystal@epa.gov]
From: Shapiro, Mike
Sent: Mon 3/14/2016 8:00:21 PM
Subject: RE: Upcoming EWG report on mercury exposures for frequent fish consumers

Ms. Lunder,

Thank you for the information on your forthcoming report. We would like to take you up on your offer to brief us on your findings. Crystal Penman will work with you to arrange an appropriate time.

Mike Shapiro

Michael Shapiro

Deputy Assistant Administrator, Office of Water

US EPA, 4101M

1200 Pennsylvania Ave., NW

Washington, DC 20460

202-564-5700

From: Sonya Lunder [mailto:sonya@ewg.org]
Sent: Friday, March 11, 2016 12:07 PM
To: Shapiro, Mike <Shapiro.Mike@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Lape, Jeff <lape.jeff@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Upcoming EWG report on mercury exposures for frequent fish consumers

Environmental Working Group has long been concerned about the adequacy of EPA and FDA seafood advice for pregnant women. In 2014 we cautioned that women who follow the government recommendations and eat 2 to 3 seafood meals per week during pregnancy could ingest too much mercury.

Next week we are releasing a report that tested hair mercury levels for 254 women who eat 2 or more seafood meals per week. We found that 29% had hair mercury levels >= 1 part per million, roughly equivalent to the reference dose. We found that only 17% of estimated mercury ingestion was from the species presently named in the seafood advice, but that tuna (steaks, sushi, and canned albacore and light) made up 40% of the mercury in our study participants' diets.

We caution that FDA and EPA must expand mercury warnings to ensure that women who follow federal seafood advice achieve the intended benefits during pregnancy. I am attaching the upcoming hair mercury study as well a our 2014 analysis of federal seafood guidelines for your review.

I welcome the opportunity to brief your staff on the findings.

- Sonya Lunder

Sonya Lunder, MPH

Senior Analyst

Environmental Working Group

Washington DC 20009

Sonya@ewg.org

202/939-9129

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Shapiro, Mike
Sent: Mon 3/14/2016 12:23:44 PM
Subject: RE: Upcoming EWG report on mercury exposures for frequent fish consumers

Betsy,

Thanks, I will respond with an invitation and have Crystal schedule.

Mike

Michael Shapiro
Deputy Assistant Administrator, Office of Water
US EPA, 4101M
1200 Pennsylvania Ave., NW
Washington, DC 20460
202-564-5700

-----Original Message-----
From: Southerland, Elizabeth
Sent: Monday, March 14, 2016 7:35 AM
To: Shapiro, Mike <Shapiro.Mike@epa.gov>
Subject: Re: Upcoming EWG report on mercury exposures for frequent fish consumers

Ex. 5 - Deliberative Process

Sent from my iPhone

> On Mar 13, 2016, at 7:47 PM, Shapiro, Mike <Shapiro.Mike@epa.gov> wrote:
>
> Betsy,
>
> **Ex. 5 - Deliberative Process**
>
> Mike
>
> Michael Shapiro
> Deputy Assistant Administrator, Office of Water US EPA, 4101M
> 1200 Pennsylvania Ave., NW
> Washington, DC 20460
> 202-564-5700
>
> From: Sonya Lunder [mailto:sonya@ewg.org]
> Sent: Friday, March 11, 2016 12:07 PM
> To: Shapiro, Mike <Shapiro.Mike@epa.gov>; Southerland, Elizabeth
> <Southerland.Elizabeth@epa.gov>; Lape, Jeff <lape.jeff@epa.gov>;
> Larimer, Lisa <Larimer.Lisa@epa.gov>
> Subject: Upcoming EWG report on mercury exposures for frequent fish
> consumers
>
>
> Environmental Working Group has long been concerned about the adequacy of EPA and FDA seafood advice for pregnant women. In 2014 we cautioned that women who follow the government

recommendations and eat 2 to 3 seafood meals per week during pregnancy could ingest too much mercury.
>
>
>
> Next week we are releasing a report that tested hair mercury levels for 254 women who eat 2 or more seafood meals per week. We found that 29% had hair mercury levels >= 1 part per million, roughly equivalent to the reference dose. We found that only 17% of estimated mercury ingestion was from the species presently named in the seafood advice, but that tuna (steaks, sushi, and canned albacore and light) made up 40% of the mercury in our study participants' diets.
>
>
>
> We caution that FDA and EPA must expand mercury warnings to ensure that women who follow federal seafood advice achieve the intended benefits during pregnancy. I am attaching the upcoming hair mercury study as well a our 2014 analysis of federal seafood guidelines for your review.
>
> I welcome the opportunity to brief your staff on the findings.
>
> - Sonya Lunder
>
> Sonya Lunder, MPH
> Senior Analyst
> Environmental Working Group
> Washington DC 20009
>
> Sonya@ewg.org<mailto:Sonya@ewg.org>
> 202/939-9129
>
> <EWG_Embargoed-MercuryHair_2015.pdf>
> <US_Gives_Seafood_Eaters_Flawed_Advice_on_Mercury.pdf>

From: Gentry, Nathan
Location: 41213 RRB; call-in: Ex. 6 - Personal Privacy
Importance: Normal
Subject: Fish Advice
Start Date/Time: Fri 11/13/2015 6:15:00 PM
End Date/Time: Fri 11/13/2015 7:15:00 PM

To: Sinks, Tom[Sinks.Tom@epa.gov]
From: Deener, Kathleen
Sent: Wed 9/28/2016 4:00:28 PM
Subject: fish/mercury
Draft of peer review report on FDA-EPA fish advice
Changes to fish advice

Hi Tom – Attached are the relevant emails and documents from OW on the fish advice. Let me know what you think.

Thanks!

Kacee

To: Katz, Stacey[Katz.Stacey@epa.gov]; Robarge, Gail[Robarge.Gail@epa.gov]
Cc: Sinks, Tom[Sinks.Tom@epa.gov]
From: Sinks, Tom
Sent: Tue 3/1/2016 9:22:43 PM
Subject: Hg and fish - more info than you want
RE: Meet via phone with Tom today or tomorrow?
Fish and Hg - some follow up information
need some short term immediate support for Tom B
FW: information on Hg and fish for today's discussion
RE: Advisory Graphics - All Fish and Tuna
Follow up fish-chart-mercury-seafood-2
FW: 12/3 Fish Advice Meeting Prep
Re: Dietary Guidelines for Americans 2015

You should be able to piece together the most recent Fish advisory story from these emails. It starts with the OW briefing for Stan and ends with the actual guidance released in the USDA/HHS Dietary Guidelines released in January. Feel free to touch base with help interpreting. Also much of this has not been released outside of EPA so be careful how you use it.

Thomas Sinks, Ph.D.

Director, Office of the Science Advisor

Environmental Protection Agency

1200 Pennsylvania Ave NW

Room 41251 RRB, MC 8105 R

Washington DC, 20460

office: (202) 564-6811 mobile: (404) 226-6288

email: sinks.tom@epa.gov

WHICH FISH AND HOW MUCH?

(Estimates of servings for a 130 lb. woman)

VERY HIGH MERCURY

More than 0.5 Parts per million

Eat Rarely

Swordfish

Bluefin tuna

Tilefish (Gulf of Mexico)

King Mackerel

Shark

HIGH MERCURY

Between 0.25 and 0.5 ppm

About 2 times per month

Bigeye Tuna

Grouper

Chilean Sea Bass

Yellowfin Tuna

Albacore Tuna (solid white)

Bluefish

Wild Striped Bass

MEDIUM MERCURY

Between 0.1 and 0.25 ppm

Up to once per week

Mahi-Mahi

Ocean Perch

Pacific Cod

Halibut

Skipjack Tuna (chunk light)

Lobster

Snappers

Flounder

LOW MERCURY

Less than 0.1 ppm

2-3 times per week

*Good source of Omega-3 fatty acids

Sardines*

Arctic Char

Squid

Anchovies*

Salmon*

Catfish (farmed)

Herring*

Trout* (farmed)

Atlantic Mackerel*

Clams

Shrimp

Mussels*

Tilapia

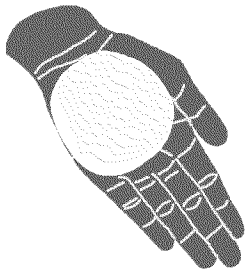
Scallops

Sole

Pollock

Oysters*

Portion guide



1 serving = 4 to 6 oz. This is roughly the size and thickness of the palm of your hand.

About 2 servings per week (8-12 oz.) of a fish that is low in mercury meets the U.S. Dietary Guidelines, American Heart Association and Environmental Protection Agency/Food and Drug Administration advice for fish consumption.

The "at risk" groups:

Pregnant or breastfeeding women and young children should eat ONLY low mercury fish.

For children under 12: Estimate about 1 oz. per 20 lbs. of body weight for a child who is not overweight. For example: a 40 pound child could eat a 2 ounce serving.

Karimi et al., 2012, Environmental Health Perspectives, A quantitative synthesis of mercury in commercial seafood and implications for exposure in the U.S.

Graphic by John Blanchard, 2015

To: Greene, Mary[greene.mary@epa.gov]; Anand Mudambi[Mudambi.Anand@epa.gov]
Cc: Sinks, Tom[Sinks.Tom@epa.gov]
From: Sinks, Tom
Sent: Thur 9/24/2015 1:13:30 PM
Subject: need some short term immediate support for Tom B
FISH_CHART_V_9.2.pdf
FDA-EPA Fish Advice briefing for DA.PPTX
FISH_CHART_H_9.2.pdf

.....
;;;;;
Tom Burke asked Fred Hauchman, Kacee Deener, and I to support him in evaluating the underpinnings of these draft communications materials proposed for release in the next few weeks. Fred is going to deal with the underlying risk assessment issues. Kacee is going to evaluate the public comments that have been received.

Ex. 5 - Deliberative Process

From: Deener, Kathleen
Sent: Wednesday, September 23, 2015 2:08 PM
To: Hauchman, Fred; Sinks, Tom
Subject: RE: Meet via phone with Tom today or tomorrow?

Here are the materials from yesterday.

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Hauchman, Fred
Sent: Wednesday, September 23, 2015 2:01 PM
To: Sinks, Tom
Cc: Deener, Kathleen
Subject: Re: Meet via phone with Tom today or tomorrow?

4:00 works. I'll call in from RTP. Would you forward the briefing materials that were used yesterday?

Sent from my iPhone

On Sep 23, 2015, at 12:18 PM, Sinks, Tom <Sinks.Tom@epa.gov> wrote:

> Both times work for me.
>
> **From:** Deener, Kathleen
> **Sent:** Wednesday, September 23, 2015 12:16 PM
> **To:** Sinks, Tom; Hauchman, Fred
> **Subject:** Meet via phone with Tom today or tomorrow?
>
> Hi Tom and Fred –
>
> I'm going to set up a 30 minute conversation for the three of us to talk with Tom B. about the EPA-FDA fish consumption advice. The two times available are today at 4:00 or tomorrow at 1:00. Fred – you're booked during both of those times, but it looks like you're in all-day meetings. Would you be able to step out for 30 minutes? If so, which time do you prefer?
>
> Kacee Deener, MPH
>
> Senior Science Advisor
>
> Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

To: Sinks, Tom[Sinks.Tom@epa.gov]; Burke, Thomas[Burke.Thomas@epa.gov]
From: Deener, Kathleen
Sent: Thur 2/11/2016 3:58:38 PM
Subject: FW: Dr Oz article on mercury in fish
Dr. Oz Fish Article.pdf
Fish Advice Hg Trend Memo_FINAL_2016 02 01.pdf

FYI – A Dr. Oz article on fish and some fish tissue concentration trend data from FDA.

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Wathen, John
Sent: Tuesday, February 09, 2016 9:22 AM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: FW: Dr Oz article on mercury in fish

Kaycee-

Cutsie article on our favorite subject forwarded by FDA colleagues. While I'm sending, we also received the attached trend memo on FDA's data. I thought it quite tight.

~John

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Monday, February 08, 2016 5:41 PM

To: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Bernard, Susan <Susan.Bernard@fda.hhs.gov>
Subject: Dr Oz article on mercury in fish

Hot off the press (March 2016).

Seems to support our draft advice. Notably they list the exact same high mercury fish we do, and the other categories are similar to ours but need to do a detailed cross walk.

Regards,

Debbie

To: Flowers, Lynn[Flowers.Lynn@epa.gov]; Sinks, Tom[Sinks.Tom@epa.gov]; Phillips, Linda[Phillips.Linda@epa.gov]
From: Deener, Kathleen
Sent: Tue 12/1/2015 9:07:37 PM
Subject: RE: Revised Ex. 5 - Deliberative Process fish advice

Yes, I'm working on that now. Will share a version once I have one ready.

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Flowers, Lynn
Sent: Tuesday, December 01, 2015 4:07 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>; Sinks, Tom <Sinks.Tom@epa.gov>; Phillips, Linda <Phillips.Linda@epa.gov>
Subject: RE: Revised Ex. 5 - Deliberative Process fish advice

Kacee: Thanks for sharing. Baby steps, huh?

Are you going to take a stab at editing?

Lynn

Lynn Flowers, PhD, DABT

Associate Director for Health

National Center for Environmental Assessment

US EPA

Washington, DC

703-347-8537

From: Deener, Kathleen
Sent: Tuesday, December 01, 2015 3:56 PM
To: Flowers, Lynn <Flowers.Lynn@epa.gov>; Sinks, Tom <Sinks.Tom@epa.gov>; Phillips, Linda <Phillips.Linda@epa.gov>
Subject: FW: Revised Ex. 5 - Deliberative Process fish advice

FYI

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Burke, Thomas
Sent: Tuesday, December 01, 2015 2:58 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Subject: Fwd: Revised Ex. 5 - Deliberative Process advice

Let's get to editing based on our discussion

Thomas A. Burke, PhD, MPH

Deputy Assistant Administrator

EPA Science Advisor

Office of Research and Development

202-564-6620

burke.thomas@epa.gov

Begin forwarded message:

From: "Beauvais, Joel" <Beauvais.Joel@epa.gov>
Date: December 1, 2015 at 2:54:03 PM EST
To: "Burke, Thomas" <Burke.Thomas@epa.gov>
Subject: Revised Ex. 5 - Deliberative Process **for fish advice**

Tom – Following up on our conversation Monday, I am sending along two attachments.

The first is a revised version of the Advice chart that FDA sent this week to OW staff. It reflects changes that FDA has made in response to NIH comments and internal focus testing. In brief, the changes they have already made in the draft are as follows:

Ex. 5 - Deliberative Process

The Word document I'm attaching is a revised version of Ex. 5 - Deliberative Process for the Thursday discussion. This has been revised to account both for FDA's new draft and my understanding of your suggestions on our Monday call. Please let me know if this works for you, or if not, please provide line edits so we can finalize before meeting on Thursday.

Here's a summary of the changes made Ex. 5 - Deliberative Process since our discussion Monday:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Joel

To: Burke, Thomas[Burke.Thomas@epa.gov]; Sinks, Tom[Sinks.Tom@epa.gov]
From: Deener, Kathleen
Sent: Mon 10/26/2015 4:35:23 PM
Subject: FW: information on Hg and fish for today's discussion
spreadsheet explanation 10-20-15_v2.docx
Copy of Example Calculations 10-20-15-rev.xlsx

Here are the electronic versions of the fish documents.

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Flowers, Lynn
Sent: Tuesday, October 20, 2015 12:12 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; Phillips, Linda <Phillips.Linda@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>
Subject: information on Hg and fish for today's discussion

Kacee:

There are two attachments for today's check in meeting with you:

1) A spreadsheet of calculations as requested (note that there are two tabs), and

2) A write up of the analysis and results.

I also have a short list of issues to note:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lynn Flowers, PhD, DABT

Associate Director for Health

National Center for Environmental Assessment

US EPA

Washington, DC

703-347-8537

To: Burke, Thomas[Burke.Thomas@epa.gov]; Sinks, Tom[Sinks.Tom@epa.gov]
From: Deener, Kathleen
Sent: Tue 10/20/2015 6:20:01 PM
Subject: FW: information on Hg and fish for today's discussion
spreadsheet explanation 10-20-15_v2.docx
Copy of Example Calculations 10-20-15-rev.xlsx

FYI, from NCEA.

Tom B. – I have color copies printed for you.

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Flowers, Lynn
Sent: Tuesday, October 20, 2015 12:12 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; Phillips, Linda <Phillips.Linda@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>
Subject: information on Hg and fish for today's discussion

Kacee:

There are two attachments for today's check in meeting with you:

1) A spreadsheet of calculations as requested (note that there are two tabs), and

2) A write up of the analysis and results.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lynn Flowers, PhD, DABT

Associate Director for Health

National Center for Environmental Assessment

US EPA

Washington, DC

703-347-8537

To: Burke, Thomas[Burke.Thomas@epa.gov]
Cc: Kavlock, Robert[Kavlock.Robert@epa.gov]; Sinks, Tom[Sinks.Tom@epa.gov]
From: Deener, Kathleen
Sent: Tue 10/6/2015 3:10:27 PM
Subject: FW: Quick update on FDA meeting on fish advice

Tom - FYI. I'll also print a copy for you.

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Hisel-Mccoy, Sara
Sent: Tuesday, October 06, 2015 9:57 AM
To: Deener, Kathleen; Fegley, Robert; Sinks, Tom
Cc: Southerland, Elizabeth; Barash, Shari
Subject: FW: Quick update on FDA meeting on fish advice

Kacee, Tom and Bob,

See below Lisa's summary of the meeting she and John had with FDA yesterday. Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process We will be bringing these changes up in Thursday's meeting with Stan so I wanted to make certain you and Tom Burke were aware of the latest state of play. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Sara

From: Larimer, Lisa
Sent: Monday, October 05, 2015 11:40 PM
To: Hisel-Mccoy, Sara
Cc: Wathen, John; Barash, Shari
Subject: Quick update on FDA meeting on fish advice

Sara-

I hear Ken will not be meeting with Stan until Thursday. Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process Our Monday meeting with FDA was fruitful and resulted in good changes to the advice (in more detail below). We plan to have a new version of the chart by Wednesday, if that is helpful for the Ken/Stan meeting.

Today's meeting ran long, but was very productive. Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Gentry, Nathan[Gentry.Nathan@epa.gov]; Sinks, Tom[Sinks.Tom@epa.gov]
Cc: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Corona, Elizabeth
Sent: Tue 5/10/2016 1:58:08 PM
Subject: FW: Request to meet about seafood advice for pregnant women
EWG_MercuryinSeafood.pdf

Hi Tom – Nathan is going to schedule a time in June for Tom to meet with EWG. We'll include you on the invite.

--
Elizabeth Corona, PhD, MBA

EPA / ORD / Immediate Office

(Desk) 202-564-8356

(Cell) 703-859-2608

From: Christine Hill [mailto:christine@ewg.org]
Sent: Tuesday, May 03, 2016 5:14 PM
To: Burke, Thomas <Burke.Thomas@epa.gov>; Sinks, Tom <Sinks.Tom@epa.gov>
Cc: sonya@ewg.org
Subject: Request to meet about seafood advice for pregnant women

Good Afternoon,

I hope this email finds you well.

In March, the Environmental Working Group released a report that tested hair mercury levels for 254 women who eat 2 or more seafood meals per week. We found that 29 percent of participants had hair mercury levels >= 1 part per million, roughly equivalent to EPA's reference dose.

Further, only 17% of estimated mercury ingestion was from the species presently named in the FDA/EPA seafood advice, and that tuna (steaks, sushi, and canned albacore and light) made up 40% of the mercury in our study participants' diets. The report is attached and Sonya Lunder, the author of the report, is CC'ed on this email for any follow up questions.

EWG has long been concerned about the EPA/ FDA seafood advice for pregnant women.

Would it be possible to arrange a meeting in the next few weeks to discuss our study findings and ongoing concerns about the draft seafood advice for pregnant women?

Please let me know.

Thanks,

Chris

—

Christine M. Hill

Director, Government Affairs

EWG | www.ewg.org

1436 U St. N.W. Suite 100

Washington, DC 20009

O: 202-939-9125 | C: 240-338-0987

E: Chill@ewg.org

To: Sinks, Tom[Sinks.Tom@epa.gov]
From: Sonya Lunder
Sent: Mon 5/9/2016 6:05:41 PM
Subject: Re: Request to meet about seafood advice for pregnant women

Thank you!

From: "Sinks, Tom" <Sinks.Tom@epa.gov>
Date: Monday, May 9, 2016 at 12:04 PM
To: Sonya Lunder <sonya@ewg.org>
Subject: Re: Request to meet about seafood advice for pregnant women

Let me forward the info to Tom's schedulers and see what we can do

Sent from my iPhone

On May 9, 2016, at 1:47 PM, Sonya Lunder <sonya@ewg.org> wrote:

> Thanks for your quick response. I work remotely and will be in Washington the week of May 16-20. I know that is quite soon, but if there is any chance to meet next week that would be ideal. Otherwise we can look for a date later in May.
>
> - Sonya
>
> **From:** "Sinks, Tom" <Sinks.Tom@epa.gov>
> **Date:** Monday, May 9, 2016 at 11:43 AM
> **To:** Sonya Lunder <sonya@ewg.org>
> **Cc:** "Kumar, Manisha" <Kumar.Manisha@epa.gov>, Christine Hill <christine@ewg.org>, "Deener, Kathleen" <Deener.Kathleen@epa.gov>
> **Subject:** Re: Request to meet about seafood advice for pregnant women
>
> Hi Sonya. I believe Dr Burke's staff are trying to schedule a meeting for all of us.
>
> Sent from my iPhone
>
> On May 9, 2016, at 1:31 PM, Sonya Lunder <sonya@ewg.org> wrote:
>
> > Dr. Sinks,
> >
> > I am just following up on the meeting request for Environmental Working Group to brief you on the results of our hair mercury study and discuss the draft FDA/EPA seafood advice for pregnant women. Would it be possible to arrange a meeting on the subject this month?
> >
> > Thank you,
> >
> > Sonya
> >
> > **Sonya Lunder**, MPH
> > Senior Analyst

sonya@ewg.org | 202-939-9129 | www.ewg.org

<1FB204DE-29F6-4B10-849C-3CEBD1565ADF.png>

From: Christine Hill <christine@ewg.org>
Date: Tuesday, May 3, 2016 at 3:13 PM
To: "Burke.thomas@epa.gov" <Burke.thomas@epa.gov>, "Sinks.tom@epa.gov" <Sinks.tom@epa.gov>
Cc: Sonya Lunder <sonya@ewg.org>
Subject: Request to meet about seafood advice for pregnant women

Good Afternoon,

I hope this email finds you well.

In March, the Environmental Working Group released a report that tested hair mercury levels for 254 women who eat 2 or more seafood meals per week. We found that 29 percent of participants had hair mercury levels >= 1 part per million, roughly equivalent to EPA's reference dose.

Further, only 17% of estimated mercury ingestion was from the species presently named in the FDA/EPA seafood advice, and that tuna (steaks, sushi, and canned albacore and light) made up 40% of the mercury in our study participants' diets. The report is attached and Sonya Lunder, the author of the report, is CC'ed on this email for any follow up questions.

EWG has long been concerned about the EPA/ FDA seafood advice for pregnant women.

Would it be possible to arrange a meeting in the next few weeks to discuss our study findings and ongoing concerns about the draft seafood advice for pregnant women?

Please let me know.

Thanks,

Chris

—

Christine M. Hill

Director, Government Affairs

EWG | www.ewg.org

1436 U St. N.W. Suite 100

Washington, DC 20009

O: 202-939-9125 | C: 240-338-0987

E: Chill@ewg.org

To: Sinks, Tom[Sinks.Tom@epa.gov]
Cc: Kumar, Manisha[Kumar.Manisha@epa.gov]; Christine Hill[christine@ewg.org]
From: Sonya Lunder
Sent: Mon 5/9/2016 5:31:33 PM
Subject: Re: Request to meet about seafood advice for pregnant women

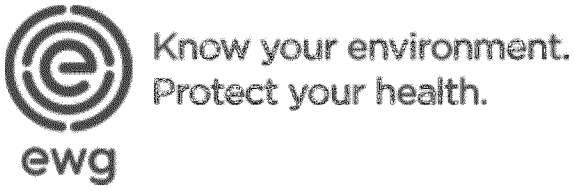
Dr. Sinks,

I am just following up on the meeting request for Environmental Working Group to brief you on the results of our hair mercury study and discuss the draft FDA/EPA seafood advice for pregnant women. Would it be possible to arrange a meeting on the subject this month?

Thank you,

Sonya

Sonya Lunder, MPH
Senior Analyst
sonya@ewg.org | 202-939-9129 | www.ewg.org



From: Christine Hill <christine@ewg.org>
Date: Tuesday, May 3, 2016 at 3:13 PM
To: "Burke.thomas@epa.gov" <Burke.thomas@epa.gov>, "Sinks.tom@epa.gov" <Sinks.tom@epa.gov>
Cc: Sonya Lunder <sonya@ewg.org>
Subject: Request to meet about seafood advice for pregnant women

Good Afternoon,

I hope this email finds you well.

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Please let me know.

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Chris

—

Christine M. Hill

Director, Government Affairs

EWG | www.ewg.org

1436 U St. N.W. Suite 100

Washington, DC 20009

O: 202-939-9125 | C: 240-338-0987

E: Chill@ewg.org

To: Deener, Kathleen[Deener.Kathleen@epa.gov]; Sinks, Tom[Sinks.Tom@epa.gov]
Cc: Corona, Elizabeth[Corona.Elizabeth@epa.gov]
From: Gentry, Nathan
Sent: Thur 5/5/2016 3:12:05 PM
Subject: RE: Request to meet about seafood advice for pregnant women

I see Tom S suggested inviting other program offices. Are we doing that, and if so, who?

Nathan Gentry

Scheduler for Tom Burke, Lek Kadeli and Bob Kavlock

EPA Office of Research and Development

Phone: 202-564-9084

Fax: 202-565-2430

From: Deener, Kathleen
Sent: Thursday, May 05, 2016 11:11 AM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Cc: Corona, Elizabeth <Corona.Elizabeth@epa.gov>; Gentry, Nathan <Gentry.Nathan@epa.gov>
Subject: RE: Request to meet about seafood advice for pregnant women

Hi Tom –

I talked with Tom B. about this today, and he is interested in meeting with this group.

Nathan – can you get back to Christine Hill and find a time that works? I know schedules are really tight for the next few weeks, so I think late May or early June would be fine.

Please include me and Tom Sinks on the invite as well. Thanks!

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Sinks, Tom
Sent: Tuesday, May 03, 2016 5:38 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Subject: Fwd: Request to meet about seafood advice for pregnant women

FYI. I'm happy to meet with EWG They have a long track record of biomomitoring using convenience sampling. My personal opinion is we should meet with them and invite other program offices and OCH.

Sent from my iPhone

Begin forwarded message:

From: "Christine Hill" <christine@ewg.org>
To: "Burke, Thomas" <Burke.Thomas@epa.gov>, "Sinks, Tom" <Sinks.Tom@epa.gov>
Cc: "sonya@ewg.org" <sonya@ewg.org>
Subject: Request to meet about seafood advice for pregnant women

Good Afternoon,

I hope this email finds you well.

In March, the Environmental Working Group released a report that tested hair mercury levels for 254 women who eat 2 or more seafood meals per week. We found that 29 percent of participants had hair mercury levels >= 1 part per million, roughly equivalent to EPA's reference dose.

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EWG has long been concerned about the EPA/ FDA seafood advice for pregnant women.

Would it be possible to arrange a meeting in the next few weeks to discuss our study findings and ongoing concerns about the draft seafood advice for pregnant women?

Please let me know.

Thanks,

Chris

—

Christine M. Hill
Director, Government Affairs
EWG | www.ewg.org<http://www.ewg.org/>
1436 U St. N.W. Suite 100
Washington, DC 20009
O: 202-939-9125 | C: 240-338-0987
E: Chill@ewg.org<mailto:Chill@ewg.org>

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Sinks, Tom
Sent: Tue 10/4/2016 5:22:22 PM
Subject: RE: fish/mercury

Ex. 5 - Deliberative Process

From: Deener, Kathleen
Sent: Tuesday, October 04, 2016 1:13 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Subject: RE: fish/mercury

Ex. 5 - Deliberative Process

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Sinks, Tom
Sent: Tuesday, October 04, 2016 12:46 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Subject: RE: fish/mercury

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Deener, Kathleen
Sent: Wednesday, September 28, 2016 12:00 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Subject: fish/mercury

Hi Tom – Attached are the relevant emails and documents from OW on the fish advice. Let me know what you think.

Thanks!

Kacee

To: Flowers, Lynn[Flowers.Lynn@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Sinks, Tom
Sent: Wed 1/6/2016 10:19:28 PM
Subject: RE: Draft **Ex. 5 - Deliberative Process** FDA-EPA fish advice

Ditto (yes)

From: Flowers, Lynn
Sent: Wednesday, January 06, 2016 5:12 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Sinks, Tom <Sinks.Tom@epa.gov>
Subject: Re: Draft **Ex. 5 - Deliberative Process** FDA-EPA fish advice

Yes...

Sent from my iPhone

On Jan 6, 2016, at 5:01 PM, Deener, Kathleen <Deener.Kathleen@epa.gov> wrote:

Lynn and Tom –

See the attached draft **Ex. 5 - Deliberative Process** I am looking at them now and I'll send you my comments and suggestions before I leave the office today. Would love your input. I've asked OW if we could have until Monday since Tom B is out this week.

Let me know if you're able to take a look and provide some comments by noon Friday.

Thanks in advance.

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Hisel-Mccoy, Sara
Sent: Tuesday, January 05, 2016 1:13 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: Draft Ex. 5 - Deliberative Process FDA-EPA fish advice

KC-

Happy new year! Attached is a draft Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process by the end of this week, so we appreciate your assistance in getting Tom's input.

Thanks,

Sara

Ex. 5 - Deliberative Process

From: Sinks, Tom
Location: Ex. 6 - Personal Privacy
Importance: Normal
Subject: Accepted: Fish advice
Start Date/Time: Mon 12/21/2015 3:45:00 PM
End Date/Time: Mon 12/21/2015 4:15:00 PM

To: McIntyre, Nathanael[McIntyre.Nathanael@epa.gov]; Brewington, Reba[Brewington.Reba@epa.gov]
Cc: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Sinks, Tom
Sent: Wed 12/9/2015 4:42:11 PM
Subject: FW: Fish Advice Meeting Request

B on the lookout for an invitation

From: Deener, Kathleen
Sent: Wednesday, December 09, 2015 9:53 AM
To: Flowers, Lynn <Flowers.Lynn@epa.gov>; Sinks, Tom <Sinks.Tom@epa.gov>
Subject: FW: Fish Advice Meeting Request

Heads up about a meeting that will be scheduled between EPA and FDA sometime soon. Tom asked that both of you attend with me.

Lynn – feel free to include Linda if you want once this is on the books.

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Gentry, Nathan
Sent: Wednesday, December 09, 2015 9:02 AM
To: Saben, Alyson L <Alyson.Saben@fda.hhs.gov>; Penman, Crystal <Penman.Crystal@epa.gov>
Cc: Crocker, Rebecca <Rebecca.Crocker@fda.hhs.gov>; Sharp, Jeremy <Jeremy.Sharp@fda.hhs.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>
Subject: RE: Fish Advice Meeting Request

Alyson,

Tom Burke does not need to attend this larger meeting. Kacee Deener would attend from ORD (along with others). Tom asked that Joel's office (Crystal) take the lead in scheduling for EPA.

Nathan Gentry

Scheduler for Tom Burke, Lek Kadeli and Bob Kavlock

EPA Office of Research and Development

Phone: 202-564-9084

Fax: 202-565-2430

From: Saben, Alyson L [mailto:Alyson.Saben@fda.hhs.gov]
Sent: Tuesday, December 08, 2015 7:03 PM
To: Gentry, Nathan <Gentry.Nathan@epa.gov>; Penman, Crystal <Penman.Crystal@epa.gov>
Cc: Crocker, Rebecca <Rebecca.Crocker@fda.hhs.gov>; Sharp, Jeremy <Jeremy.Sharp@fda.hhs.gov>
Subject: RE: Fish Advice Meeting Request
Importance: High

Hi again, Nathan and Crystal –

Circling back to see if the larger meeting between FDA and EPA subject matter experts has been confirmed for 12/14 when you said Tom Burke will be back in town, per Nathan's note below. If you could provide us with a few times/dates that work for EPA next week, we can check to make sure they work for the FDA attendees and then get back to you so that you can send out the calendar invite and meeting details, for which I've gone ahead and provided e-mail addresses for you. Please let us know, too, if the meeting will be at EPA HQ or if you wish to come to our campus. We will likely need a call-in # as well, when you send the invite out.

FDA Attendees

Jeremy Sharp - Jeremy.Sharp@fda.hhs.gov

Mike Taylor - Mike.Taylor@fda.hhs.gov

Susan Mayne - Mike.Taylor@fda.hhs.gov

Susan Bernard - Susan.Bernard@fda.hhs.gov

Debbie Smegal - Deborah.Smegal@fda.hhs.gov

Sharon Natanblut - Sharon.Natanblut@fda.hhs.gov

Sherri Dennis - Sherri.Dennis@fda.hhs.gov

Bill Jones - William.Jones@fda.hhs.gov

Thank you.

Alyson Saben, Special Assistant

Office of Policy, Planning, Legislation, and Analysis

U.S. Food & Drug Administration

301-796-8817

From: Gentry, Nathan [mailto:Gentry.Nathan@epa.gov]
Sent: Tuesday, November 24, 2015 9:00 AM
To: Saben, Alyson L; Penman, Crystal
Cc: Crocker, Rebecca
Subject: RE: Fish Advice Meeting Request

The smaller meeting you mention is scheduled for December 3 at 3:30pm. I don't believe the

larger meeting has been scheduled, and given that Tom Burke will be out December 4-11, it wouldn't be scheduled until December 14 (and he's out again December 16-18).

Nathan Gentry

Scheduler for Tom Burke, Lek Kadeli and Bob Kavlock

EPA Office of Research and Development

Phone: 202-564-9084

Fax: 202-565-2430

From: Saben, Alyson L [mailto:Alyson.Saben@fda.hhs.gov]
Sent: Monday, November 23, 2015 5:46 PM
To: Penman, Crystal <Penman.Crystal@epa.gov>; Gentry, Nathan <Gentry.Nathan@epa.gov>
Cc: Crocker, Rebecca <Rebecca.Crocker@fda.hhs.gov>
Subject: FW: Fish Advice Meeting Request

Hi Crystal and Nathan –

1. Since it is a short week this week, I wanted to check in with you to see if you have dates/times yet to offer to FDA the week of 11/30 for the EPA/FDA briefing that will include our respective staffs?

2. In addition to the meeting referenced above, at Joel's request, we also need to schedule an initial, smaller conversation Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

am presuming this one could be by telephone.

At your earliest convenience, could you send Rebecca and me dates/times that will work for each of these meetings? Could you also let us know if the larger meeting will be at EPA or here at our WO Campus?

Many thanks for your kind assistance.

Alyson Saben, Special Assistant

Office of Policy, Planning, and Legislation

U.S. Food & Drug Administration

301-796-8817

From: Saben, Alyson L
Sent: Friday, November 20, 2015 2:54 PM
To: Penman, Crystal; Gentry, Nathan
Cc: Burke, Thomas; Southerland, Elizabeth; Crocker, Rebecca; Sharp, Jeremy; Beauvais, Joel
Subject: RE: Fish Advice Meeting Request

Good Afternoon Crystal and Nathan –

I have included FDA's Manifest below. Crystal, if you'd like to check with Nathan and then provide a range of dates/times that work for all of the EPA attendees the week of 11/30, Rebecca Crocker can then float those dates and times with the FDA attendees, and provide you with consolidated options that work for FDA, as well.

Also, will the meeting be at EPA (for travel planning purposes) and will a call-in # be provided as well? If you would like to come out to our White Oak Campus in Silver Spring, MD, we would also be willing to host this meeting, just let Rebecca know.

FDA Attendees

Jeremy Sharp

Mike Taylor

Susan Mayne

Susan Bernard

Debbie Smegal

Sharon Natanblut

Sherri Dennis

Bill Jones

Thank you.

Alyson Saben, Special Assistant

Office of Policy, Planning, and Legislation

U.S. Food & Drug Administration

301-796-8817

From: Sharp, Jeremy
Sent: Thursday, November 19, 2015 9:39 PM
To: Beauvais, Joel
Cc: Burke, Thomas; Penman, Crystal; Gentry, Nathan; Southerland, Elizabeth; Crocker, Rebecca; Saben, Alyson L
Subject: RE: Fish Advice Meeting Request

Very good – I'm cc'ing Rebecca Crocker and Alyson Saben on my staff who will get you an FDA manifest tomorrow and can work with Crystal and Nathan to arrange a time. I'll reach out to Mike to confirm his ability to participate.

Thanks!

From: Beauvais, Joel [mailto:Beauvais.Joel@epa.gov]
Sent: Thursday, November 19, 2015 9:37 PM
To: Sharp, Jeremy
Cc: Burke, Thomas; Penman, Crystal; Gentry, Nathan; Southerland, Elizabeth
Subject: Fish Advice Meeting Request

Hi, Jeremy – As we discussed earlier, EPA would like to schedule a policy discussion with you and relevant staff on the draft Seafood Consumption Advice. Thanks to the holiday next week, that would probably have to take place the week of 11/30 at the earliest. I have included a tentative EPA manifest below, which includes folks from my staff, as well as Dr. Thomas Burke, the EPA Science Advisor and lead for our Office of Research and Development.

Dr. Burke has requested that FDA include in the meeting Deputy Commissioner Michael Taylor, who Dr. Burke knows and with whom I believe he will have been in touch about this.

I am cc'ing on this message Crystal Penman, who handles scheduling for me, as well as Nathan Gentry, who does so for Dr. Burke – in hopes that they can work with your scheduler to set up a meeting in due course.

Joel

EPA Manifest:

Thomas Burke

Kathleen Deener

Joel Beauvais

Betsy Southerland

Betsy Behl

Lisa Larimer

To: Burke, Thomas[Burke.Thomas@epa.gov]
From: Sinks, Tom
Sent: Thur 10/29/2015 12:48:36 AM
Subject: Re: Follow up fish-chart-mercury-seafood-2

So what happened today?

Fred H stopped by and asked if I was interested in helping on tire crum. Happy to help. Seems to me an

Ex. 5 - Deliberative Process

Sent from my iPhone

> On Oct 28, 2015, at 6:30 PM, Burke, Thomas <Burke.Thomas@epa.gov> wrote:
>

Ex. 5 - Deliberative Process

>
> Tom
>
> Thomas A. Burke, PhD, MPH
> Deputy Assistant Administrator
> EPA Science Advisor
> Office of Research and Development
> 202-564-6620
> burke.thomas@epa.gov
>
>>
>>
>>
> <fish-chart-mercury-seafood-2.pdf>
>>
>>
>>
>> Sent from my iPhone

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
Cc: Sinks, Tom[Sinks.Tom@epa.gov]
From: Sinks, Tom
Sent: Thur 10/22/2015 12:42:50 PM
Subject: Main Messages about Fish Advice_10 16 15.docx
Main Messages about Fish Advice_10 16 15.docx

Some suggested edits. Nice job. I

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)[kxs5@cdc.gov]
From: Sinks, Tom
Sent: Tue 10/6/2015 1:28:55 PM
Subject: RE: few thoughts on mercury in fish advice

The report is from the FDA report on fish consumption – Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process If you have something easily accessible send me that.

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) [mailto:kxs5@cdc.gov]
Sent: Tuesday, October 06, 2015 9:26 AM
To: Sinks, Tom
Subject: RE: few thoughts on mercury in fish advice

What charts? From the scientific report that is on line?

From: Sinks, Tom [mailto:Sinks.Tom@epa.gov]
Sent: Tuesday, October 06, 2015 9:20 AM
To: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>
Subject: FW: few thoughts on mercury in fish advice

Can you send me the charts for highlighted references below? Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

From: Deener, Kathleen
Sent: Tuesday, October 06, 2015 9:06 AM
To: Burke, Thomas; Sinks, Tom
Subject: RE: few thoughts on mercury in fish advice

Ex. 5 - Deliberative Process

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

Begin forwarded message:

From: "vanDrunick, Suzanne" <vanDrunick.Suzanne@epa.gov>
Date: October 5, 2015 at 6:28:07 PM EDT
To: "Burke, Thomas" <Burke.Thomas@epa.gov>, "Kavlock, Robert" <Kavlock.Robert@epa.gov>
Subject: few thoughts on mercury in fish advice

Ex. 5 - Deliberative Process

Suzanne van Drunick, Ph.D.

National Program Director, Safe and Sustainable Water Resources

Office of Research and Development

U.S. Environmental Protection Agency

1200 Pennsylvania Ave., N.W.

Washington, DC 20460

To: Burke, Thomas[Burke.Thomas@epa.gov]
From: Sinks, Tom
Sent: Tue 10/6/2015 12:31:47 PM
Subject: RE: few thoughts on mercury in fish advice

We meet today and can discuss in person

From: Burke, Thomas
Sent: Tuesday, October 06, 2015 7:22 AM
To: Sinks, Tom
Cc: Deener, Kathleen
Subject: Fwd: few thoughts on mercury in fish advice

Tom,

Ex. 5 - Deliberative Process

Tom

Thomas A. Burke, PhD, MPH

Deputy Assistant Administrator

EPA Science Advisor

Office of Research and Development

202-564-6620

burke.thomas@epa.gov

Begin forwarded message:

From: "vanDrunick, Suzanne" <vanDrunick.Suzanne@epa.gov>
Date: October 5, 2015 at 6:28:07 PM EDT
To: "Burke, Thomas" <Burke.Thomas@epa.gov>, "Kavlock, Robert" <Kavlock.Robert@epa.gov>
Subject: few thoughts on mercury in fish advice

Dear Tom and Bob,

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Suzanne van Drunick, Ph.D.

National Program Director, Safe and Sustainable Water Resources

Office of Research and Development

U.S. Environmental Protection Agency

1200 Pennsylvania Ave., N.W.

Washington, DC 20460

To: Deener, Kathleen[Deener.Kathleen@epa.gov]; Gentry, Nathan[Gentry.Nathan@epa.gov]
From: Sinks, Tom
Sent: Mon 5/9/2016 6:05:55 PM
Subject: Fwd: Request to meet about seafood advice for pregnant women

C info from SL of EWG re her availability next week

Sent from my iPhone

Begin forwarded message:

From: Sonya Lunder <sonya@ewg.org>
Date: May 9, 2016 at 1:47:01 PM EDT
To: "Sinks, Tom" <Sinks.Tom@epa.gov>
Cc: "Kumar, Manisha" <Kumar.Manisha@epa.gov>, Christine Hill <christine@ewg.org>, "Deener, Kathleen" <Deener.Kathleen@epa.gov>
Subject: Re: Request to meet about seafood advice for pregnant women

Thanks for your quick response. I work remotely and will be in Washington the week of May 16-20. I know that is quite soon, but if there is any chance to meet next week that would be ideal. Otherwise we can look for a date later in May.

- Sonya

From: "Sinks, Tom" <Sinks.Tom@epa.gov>
Date: Monday, May 9, 2016 at 11:43 AM
To: Sonya Lunder <sonya@ewg.org>
Cc: "Kumar, Manisha" <Kumar.Manisha@epa.gov>, Christine Hill <christine@ewg.org>, "Deener, Kathleen" <Deener.Kathleen@epa.gov>
Subject: Re: Request to meet about seafood advice for pregnant women

Hi Sonya. I believe Dr Burke's staff are trying to schedule a meeting for all of us.

Sent from my iPhone

On May 9, 2016, at 1:31 PM, Sonya Lunder <sonya@ewg.org> wrote:

Dr. Sinks,

I am just following up on the meeting request for Environmental Working Group to brief you on the results of our hair mercury study and discuss the draft FDA/EPA seafood advice for pregnant women. Would it be possible to arrange a meeting on the subject this month?

Thank you,

Sonya

Sonya Lunder, MPH
Senior Analyst
sonya@ewg.org | 202-939-9129 | www.ewg.org

<1FB204DE-29F6-4B10-849C-3CEBD1565ADF.png>

From: Christine Hill <christine@ewg.org>
Date: Tuesday, May 3, 2016 at 3:13 PM
To: "Burke.thomas@epa.gov" <Burke.thomas@epa.gov>, "Sinks.tom@epa.gov" <Sinks.tom@epa.gov>
Cc: Sonya Lunder <sonya@ewg.org>
Subject: Request to meet about seafood advice for pregnant women

Good Afternoon,

I hope this email finds you well.

In March, the Environmental Working Group released a report that tested hair mercury levels for 254 women who eat 2 or more seafood meals per week. We found that 29 percent of participants had hair mercury levels >= 1 part per million, roughly equivalent to EPA's reference dose.

Further, only 17% of estimated mercury ingestion was from the species presently named in the FDA/EPA seafood advice, and that tuna (steaks, sushi, and canned albacore and light) made up 40% of the mercury in our study participants' diets. The report is attached and Sonya Lunder, the author of the report, is CC'ed on this email for any follow up questions.

EWG has long been concerned about the EPA/ FDA seafood advice for pregnant women.

Would it be possible to arrange a meeting in the next few weeks to discuss our study findings and ongoing concerns about the draft seafood advice for pregnant women?

Please let me know.

Thanks,

Chris

—

Christine M. Hill

Director, Government Affairs

EWG | www.ewg.org

1436 U St. N.W. Suite 100

Washington, DC 20009

O: 202-939-9125 | C: 240-338-0987

E: Chill@ewg.org

To: sonya@ewg.org[sonya@ewg.org]
Cc: Kumar, Manisha[Kumar.Manisha@epa.gov]; Christine Hill[christine@ewg.org]; Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Sinks, Tom
Sent: Mon 5/9/2016 5:43:10 PM
Subject: Re: Request to meet about seafood advice for pregnant women

Hi Sonya. I believe Dr Burke's staff are trying to schedule a meeting for all of us.

Sent from my iPhone

On May 9, 2016, at 1:31 PM, Sonya Lunder <sonya@ewg.org> wrote:

> Dr. Sinks,
>
> I am just following up on the meeting request for Environmental Working Group to brief you on the results of our hair mercury study and discuss the draft FDA/EPA seafood advice for pregnant women. Would it be possible to arrange a meeting on the subject this month?
>
> Thank you,
>
> Sonya
>
> **Sonya Lunder**, MPH
> Senior Analyst
> sonya@ewg.org | 202-939-9129 | www.ewg.org
>
> <1FB204DE-29F6-4B10-849C-3CEBD1565ADF.png>
>
> **From:** Christine Hill <christine@ewg.org>
> **Date:** Tuesday, May 3, 2016 at 3:13 PM
> **To:** "Burke.thomas@epa.gov" <Burke.thomas@epa.gov>, "Sinks.tom@epa.gov" <Sinks.tom@epa.gov>
> **Cc:** Sonya Lunder <sonya@ewg.org>
> **Subject:** Request to meet about seafood advice for pregnant women
>
> Good Afternoon,
>
> I hope this email finds you well.
>
> In March, the Environmental Working Group released a report that tested hair mercury levels for 254 women who eat 2 or more seafood meals per week. We found that 29 percent of participants had hair mercury levels >= 1 part per million, roughly equivalent to EPA's reference dose.
>
> Further, only 17% of estimated mercury ingestion was from the species presently

named in the FDA/EPA seafood advice, and that tuna (steaks, sushi, and canned albacore and light) made up 40% of the mercury in our study participants' diets. The report is attached and Sonya Lunder, the author of the report, is CC'ed on this email for any follow up questions.

EWG has long been concerned about the EPA/ FDA seafood advice for pregnant women.

Would it be possible to arrange a meeting in the next few weeks to discuss our study findings and ongoing concerns about the draft seafood advice for pregnant women?

Please let me know.

Thanks,

Chris

—

Christine M. Hill

Director, Government Affairs

EWG | www.ewg.org

1436 U St. N.W. Suite 100

Washington, DC 20009

O: 202-939-9125 | C: 240-338-0987

E: Chill@ewg.org

To: McRae, Evelyn[McRae.Evelyn@epa.gov]; Kramer, Bill[Kramer.Bill@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]; Washington, Evelyn[Washington.Evelyn@epa.gov]
From: John Wathen
Sent: Sat 3/28/2015 10:39:24 AM
Subject: RE: NWQSB items for OD list

FSBOB items for OD meeting

No developments in fish tissue studies this week. SHPD staff continue to review comments on the draft FDA/EPA fish advice ahead of the planned 4/14 second meeting Ex. 5 - Deliberative Process

Beach Program

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Data verification is proceeding at a brisk pace and reviews of a limited set of verified data have been completed.

~John

On Fri, 3/27/15, Kramer, Bill <Kramer.Bill@epa.gov> wrote:

Subject: RE: NWQSB items for OD list
To: "McRae, Evelyn" <McRae.Evelyn@epa.gov>
Cc: "Wathen, John" <Wathen.John@epa.gov>, "'John Wathen'" <jwath@yahoo.com>
Date: Friday, March 27, 2015, 10:10 AM

John did not leave me anything - I'll
see if he responds

>< ((('>

Bill Kramer
202-566-0385

-----Original Message-----
From: McRae, Evelyn
Sent: Friday, March 27, 2015 10:00 AM
To: Barash, Shari
Cc: Buffo, Corey; Kramer, Bill; McRae, Evelyn
Subject: RE: NWQSB items for OD list

Shari ,Thank You.

Corey and Bill please send any items for the 3/30/2015 OD
meeting. Thanks, Evelyn M.

-----Original Message-----
From: Barash, Shari
Sent: Friday, March 27, 2015 9:55 AM
To: McRae, Evelyn
Cc: Robiou, Grace
Subject: NWQSB items for OD list

NWQSB items

For Sara:
1. Grace on leave all week, Shari acting

WQS Reg Rev

Ex. 5 - Deliberative Process

Beach/Rec Criteria Implementation
-Tracy Bone will attend R3 Beach Coord meeting hosted by Maryland Dept of Env to talk about Beach Program and Rec Criteria implementation

Fish/Beach Mgnt retreat
- retreat at TRG on 3/23 to clarify roles and responsibilities for Shari, John, Lisa, and permanent BC
- retreat was successful
- split transition into 3 phases (Shari acting BC with Reg rev, Shari acting BC post Reg rev, and permanent BC)

Sent from my iPhone

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
Cc: Buffo, Corey[Buffo.Corey@epa.gov]; Washington, Evelyn[Washington.Evelyn@epa.gov]; McRae, Evelyn[McRae.Evelyn@epa.gov]
From: McRae, Evelyn
Sent: Wed 6/29/2016 1:56:57 PM
Subject: FW: REMINDER: OST's topics for Joel's email to the Administrator

Corey, Thanks

From: Buffo, Corey
Sent: Wednesday, June 29, 2016 9:53 AM
To: McRae, Evelyn <McRae.Evelyn@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Cc: Washington, Evelyn <Washington.Evelyn@epa.gov>
Subject: RE: REMINDER: OST's topics for Joel's email to the Administrator

That is a document being drafted and coordinated by Joel's Office, through Ellen. We are only providing comments back to Ellen. If they need a program to give them a blurb about their effort, maybe OWOW, as the nutrients lead, can do that? I like to be helpful, of course, but we are way down the food chain on this one.

From: McRae, Evelyn
Sent: Wednesday, June 29, 2016 9:49 AM
To: Buffo, Corey <Buffo.Corey@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Cc: Washington, Evelyn <Washington.Evelyn@epa.gov>; McRae, Evelyn <McRae.Evelyn@epa.gov>
Subject: FW: REMINDER: OST's topics for Joel's email to the Administrator

Shari and/or Corey, if the below belongs to SHPD (in red), please respond to Octavia by 1pm today. Thanks, Evelyn M.

Which Division (SHPD or HECD) is working on the blurb regarding EPA's continued commitment to working with the states on a nutrient reduction strategy? Please submit your write-up by 1pm today.

From: Conerly, Octavia
Sent: Wednesday, June 29, 2016 9:44 AM
To: McRae, Evelyn <McRae.Evelyn@epa.gov>
Subject: FW: REMINDER: OST's topics for Joel's email to the Administrator

Thanks for checking on this.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Flaherty, Colleen
Sent: Wednesday, June 29, 2016 9:38 AM
To: Conerly, Octavia <Conerly.Octavia@epa.gov>; Washington, Evelyn <Washington.Evelyn@epa.gov>
Subject: RE: REMINDER: OST's topics for Joel's email to the Administrator

That's SHPD, right Evelyn?

From: Conerly, Octavia
Sent: Wednesday, June 29, 2016 8:52 AM
To: Flaherty, Colleen <Flaherty.Colleen@epa.gov>; Washington, Evelyn <Washington.Evelyn@epa.gov>
Subject: REMINDER: OST's topics for Joel's email to the Administrator

This is a friendly reminder. I have the write-up Ex. 5 - Deliberative Process Thank you Colleen.

Which Division (SHPD or HECD) is working on the blurb regarding EPA's continued commitment to working with the states on a nutrient reduction strategy? Please submit your write-up by 1pm today. Thanks in advance.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Conerly, Octavia
Sent: Monday, June 27, 2016 10:04 AM
To: Flaherty, Colleen <Flaherty.Colleen@epa.gov>; Washington, Evelyn <Washington.Evelyn@epa.gov>
Cc: Zipf, Lynn <Zipf.Lynn@epa.gov>
Subject: OST's topics for Joel's email to the Administrator

Good morning All,

Joel has requested the following blurbs from OST to be included in his weekly

email to the Administrator this week. Please submit your write-ups to me by 1pm on Wednesday. Thanks in advance. If you have any questions, please contact me.

Draft Topics List for 6/30 OW Weekly Email to the Administrator

- **Joel's Travel/Speaking Schedule —Joel leaves for Singapore 7/8**

Ex. 5 - Deliberative Process

Here is Joel's email to the Administrator from last week:

Administrator and company – Here's the OW weekly update. Please note that I will be out of the office on annual leave Thursday afternoon and all day Friday with little to no email access until July 5. Ellen and Mike will be accessible. Had a good session this morning with the Mayors Water Council at the US Conference of Mayors meeting in Indy and will be working with Mark to pursue follow up engagement with them on drinking water issues.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

or

FDA Seafood Advice: After a hiatus of several months, we heard back from FDA that they are interested in moving forward with peer review of the draft advice. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Selenium Ambient Water Quality Criteria for the Protection of Aquatic Life: On Friday, I anticipate signing the final updated aquatic life water quality criterion for selenium in freshwater. The final criterion takes into account selenium bioaccumulation in aquatic food webs and is expressed in terms of two fish tissue elements and two water column elements. EPA will recommend that states include all four elements in their water quality standards in a hierarchal fashion reflecting the primacy of fish tissue elements over water column elements. In the development of this criterion, EPA partnered with multiple offices within the agency, USGS, and several Regions. This document underwent two rounds of public comment and external peer review. As I mentioned in my earlier email on this and discussed with Stan and Laura in our briefing last week, OW, ORD, and the Regions are working to produce a set of technical support documents designed to assist states and other stakeholders in implementation of the final selenium criterion. We plan to release these implementation documents later in 2016 and will conduct additional outreach at that time.

Ex. 5 - Deliberative Process

MOU for Permitting Offshore Aquaculture Activities in Federal Waters of the Gulf of Mexico: On Friday, we plan to announce the release of an MOU for permitting offshore aquaculture activities in federal waters of the Gulf of Mexico. The RAs in Regions 4 and 6 are the signatories for EPA. The MOU establishes a cooperative agreement amongst seven agencies - EPA, the National Marine Fisheries Service, the U.S. Army Corps of Engineers, the U.S. Coast Guard, the Bureau of Ocean Energy Management, Bureau of Safety and Environmental Enforcement, and the U.S. Fish and Wildlife Service - and reflects a shared commitment to streamline the permitting process for marine aquaculture operations in federal waters of the Gulf of Mexico. The goal of the MOU is to facilitate efficient, effective, and synchronized interagency reviews of permit applications that will reduce the time required to render permit decisions on proposed offshore aquaculture operations while minimizing environmental impacts and ensuring a transparent permitting process for the offshore aquaculture industry in the Gulf. This is a non controversial good government step.

Octavia Conerly

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Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

To: Barash, Shari[Barash.Shari@epa.gov]; Buffo, Corey[Buffo.Corey@epa.gov]; Keating, Jim[Keating.Jim@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Vlcan, Manjali[Vlcan.Manjali@epa.gov]; Wilcut, Lars[Wilcut.Lars@epa.gov]
Cc: McRae, Evelyn[McRae.Evelyn@epa.gov]; Washington, Evelyn[Washington.Evelyn@epa.gov]
From: McRae, Evelyn
Sent: Fri 6/24/2016 1:56:34 PM
Subject: RE: Reminder: SHPD weekly OD notes due tomorrow (6/24/2016). Thanks, Evelyn M.

Question: do we have any shout outs?

From: Barash, Shari
Sent: Friday, June 24, 2016 9:46 AM
To: Buffo, Corey <Buffo.Corey@epa.gov>; McRae, Evelyn <McRae.Evelyn@epa.gov>; Keating, Jim <Keating.Jim@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Vlcan, Manjali <Vlcan.Manjali@epa.gov>; Wilcut, Lars <Wilcut.Lars@epa.gov>
Subject: RE: Reminder: SHPD weekly OD notes due tomorrow (6/24/2016). Thanks, Evelyn M.

One more item for NB:

Citizen Science Photo Contest

- NEEF announced the winners of the Citizen Science Water Quality Photo Contest on Friday (6/24)

- Shari will send the link around to OST to see the winners and the other entries

- Ibrahim will provide a tweet to OW for sharing the link and announcement on EPA social media

Shari Z. Barash

Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Buffo, Corey
Sent: Friday, June 24, 2016 9:01 AM
To: Barash, Shari <Barash.Shari@epa.gov>; McRae, Evelyn <McRae.Evelyn@epa.gov>; Keating, Jim <Keating.Jim@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Vlcan, Manjali <Vlcan.Manjali@epa.gov>; Wilcut, Lars <Wilcut.Lars@epa.gov>
Subject: RE: Reminder: SHPD weekly OD notes due tomorrow (6/24/2016). Thanks, Evelyn M.

Regional Branch

- □□□□□□□□ ANPRM;
  - Is ready for Sara review.
  - Consultation letter was routed to Joel, should have been signed by the time of this reading. We will be sending to tribes, OITA working with NCAI to get an announcement out there.
- □□□□□□□□ MO NNC meeting request is ready for signature, should be with Betsy S now or she already signed it.
- □□□□□□□□ Reinterpretation rule implementation template was posted, sent to all the Regions, in addition to the webinar announcement. Felicia is sending the latter to the tribes.
- □□□□□□□□ CTR should be signed this week. Will do a shout out for next Monday.

From: Barash, Shari
Sent: Friday, June 24, 2016 8:43 AM
To: McRae, Evelyn <McRae.Evelyn@epa.gov>; Buffo, Corey <Buffo.Corey@epa.gov>; Keating, Jim <Keating.Jim@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Vlcan, Manjali <Vlcan.Manjali@epa.gov>; Wilcut, Lars <Wilcut.Lars@epa.gov>
Subject: RE: Reminder: SHPD weekly OD notes due tomorrow (6/24/2016). Thanks, Evelyn M.

National Branch Items

Fish Advice

- Any news on Tom Burke response?

Fish Consumption Survey Guidance

Ex. 5 - Deliberative Process

- After 6/28 meeting with Ellen, we will submit a briefing request for Joel.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Marine Sanitary Survey App

- Ready for Google Play, but OEI is working out new terms and conditions for EPA apps generally

- We are figuring out who else at EPA has apple apps to see if we can band together and get OEI to move quickly

- We would like to announce release our app on both systems at the same time

National WQS Program Meeting

- Meeting planning is moving along well

- Topics have been set for the agenda Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

- Volunteers being assigned to subgroups

- Subgroups beginning to discuss topics

Selenium Implementation Guidance

- Workgroup members and offices are due to have their documents ready for one-voice editing by June 28th

Shari Z. Barash

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barash.shari@epa.gov

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Cc: McRae, Evelyn <McRae.Evelyn@epa.gov>
Subject: Reminder: SHPD weekly OD notes due tomorrow (6/24/2016). Thanks, Evelyn M.

To: Barash, Shari[Barash.Shari@epa.gov]; Buffo, Corey[Buffo.Corey@epa.gov]; Keating, Jim[Keating.Jim@epa.gov]
Cc: Washington, Evelyn[Washington.Evelyn@epa.gov]
From: Hisel-Mccoy, Sara
Sent: Wed 6/22/2016 7:50:22 PM
Subject: Feedback from my general with Betsy S and Jeff L

Fish Advice – nothing yet from Tom but Joel did send it to him

Fish Consumption Survey guidance – we will need to brief Joel after we have gotten comments back. We can talk more at our general.

MO NNC – Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Decision Lens – Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process We will need to brief betsy later this summer – before the national meeting – august sometime I would think.

Sara

To: Washington, Evelyn[Washington.Evelyn@epa.gov]
From: Gerstein, Arielle
Sent: Fri 12/11/2015 6:37:15 PM
Subject: Joint FDA/EPA Hg Fish Advice

Hi Evelyn,

Sharon told me that at Monday's meeting she heard the Joint FDA/EPA Hg Fish Advice needs to be moved out. Do you have any idea/guess as to what date it should be moved?

Thanks,

Arielle

Arielle Gerstein

Office of Science and Technology

Office of Water, U.S. EPA

(202) 566-1868

To: Keating, Jim[Keating.Jim@epa.gov]; Washington, Evelyn[Washington.Evelyn@epa.gov]
Cc: Anderson, Danielle[Anderson.Danielle@epa.gov]; McRae, Evelyn[McRae.Evelyn@epa.gov]
From: Fleisig, Erica
Sent: Mon 10/24/2016 1:27:21 PM
Subject: RE: OD list for National Branch

I sent one to Evelyn M last week – Sara wanted us to ask Betsy S's direction re: the FL human health criteria briefing for Joel (what should it cover, now that we have updated info from FDEP). Sorry didn't see this before 9, hope this made the list…

From: Keating, Jim
Sent: Monday, October 24, 2016 8:55 AM
To: Washington, Evelyn <Washington.Evelyn@epa.gov>
Cc: Fleisig, Erica <Fleisig.Erica@epa.gov>; Anderson, Danielle <Anderson.Danielle@epa.gov>
Subject: Re: OD list for National Branch

Ah, I guess not. The meeting is in 10 min, right?

Ex. 5 - Deliberative Process We also have a WA Rule blue folder moving this week...

If I had known Friday, I could have put something together. Sorry!

Sent from my iPhone

On Oct 24, 2016, at 8:42 AM, Washington, Evelyn <Washington.Evelyn@epa.gov> wrote:

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>
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> **Sent:** Friday, October 21, 2016 4:43 PM
> **To:** McRae, Evelyn <McRae.Evelyn@epa.gov>; Washington, Evelyn <Washington.Evelyn@epa.gov>
> **Cc:** Moore, Keara <Moore.Keara@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wilcut, Lars <Wilcut.Lars@epa.gov>; Vlcan, Manjali <Vlcan.Manjali@epa.gov>
> **Subject:** OD list for National Branch

National Branch Items

1. New employees started on 10/17 (we have sent shout outs) – John Healey and Samar Khoury – we can bring them to the first OST staff meeting in November; Melissa Dreyfus will start in early November and Heather will be back on Nov 2nd.

2. Manjali is teleworking most of the week

Fish

Advice

- Meeting with Tom Burke and Joel on Oct 26

- Lisa Larimer will represent SHPD with Betsy S to keep meeting small

MOU

- Meeting with staff level on Nov 1 in College Park (Shari and Lisa attending)

Fish Consumption Survey Guidance

- Continuing to work to respond to comments, contractor revisions back to EPA for review, contractor proposal to address NCI vs FFQ method issues

- Had good call with R10 to plan "consultation workshop" with R10 tribes as requested by Northwest Indian Fisheries Commission, aiming to have meeting/webinar first week of December

WI MDV

- HQ finishing edits on action letter

- Call with R5 to work out an outstanding issues on 10/25

Ex. 5 - Deliberative Process

WQS Academy

- Large number of registrations! (150 – which is 80 more than we can fit)

- Notified those who are accepted for Dec and let others know they will be admitted to April or May Academy

WQS Roundtable – led by R3

- Topic related to work with DRBC

Shari Z. Barash

Chief

National Branch

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barash.shari@epa.gov

To: Washington, Evelyn[Washington.Evelyn@epa.gov]
From: McRae, Evelyn
Sent: Fri 8/21/2015 6:11:05 PM
Subject: OD notes
SHPD Monday OD List 08-24-2015.docx

Monday, August 24, 2015

OD List

REGIONAL – Corey

Ex. 5 - Deliberative Process

NATIONAL – Shari

WQS Reg Revision:

- Published in the FR on Friday, August 21
- All materials (including comment response) are in the docket
- We let our partners know that it has published
- Now planning outreach webinars
- Meeting this week with staff to plan update to Academy materials

EPA-FDA Fish Advice:

- The materials (chart, Q&As, response to comments, etc.) have cleared FDA Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

- Ex. 5 - Deliberative Process
  Administrator's briefing (including the communications folks, per Betsy's Friday report out from OW staff).

Other:

- Ex. 5 - Deliberative Process
- WQS 101 and WQS for Tribal Land training at TLEF conference was well received.

To: McRae, Evelyn[McRae.Evelyn@epa.gov]
Cc: Washington, Evelyn[Washington.Evelyn@epa.gov]
From: Barash, Shari
Sent: Fri 8/21/2015 3:18:19 PM
Subject: OD list for National Branch

WQS Reg Revision

- Published in the FR on Friday, August 21

- All materials (including comment response) are in the docket

- We let our partners know that it has published

-Now planning outreach webinars

-Meeting this week with staff to plan update to Academy materials

EPA-FDA fish advice

- The materials (chart, Q&As, response to comments, etc.) have cleared FDA Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Other

Ex. 5 - Deliberative Process

-WQS 101 and WQS for Tribal Lands training at TLEF conference was well received.

Shari Z. Barash
Associate Chief
National Water Quality Standards Branch
Office of Science & Technology

Office of Water
US EPA
Washington, DC
barash.shari@epa.gov
202-566-0996

To: Washington, Evelyn[Washington.Evelyn@epa.gov]
From: Conerly, Octavia
Sent: Tue 3/22/2016 3:29:23 PM
Subject: RE: CORRECTION: FYI: Advocates Cite New Mercury Study To Urge Updated EPA, FDA Fish Guide

I had a brain fart this morning.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Washington, Evelyn
Sent: Tuesday, March 22, 2016 11:22 AM
To: Conerly, Octavia <Conerly.Octavia@epa.gov>
Subject: RE: CORRECTION: FYI: Advocates Cite New Mercury Study To Urge Updated EPA, FDA Fish Guide

Its SHPD... but looks like you figured that out.

From: Conerly, Octavia
Sent: Tuesday, March 22, 2016 8:25 AM
To: OST-EVERYONE <OSTEVERYONE@epa.gov>
Subject: CORRECTION: FYI: Advocates Cite New Mercury Study To Urge Updated EPA, FDA Fish Guide

It's not EAD that works on this. Sorry, EAD!

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

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Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Conerly, Octavia
Sent: Tuesday, March 22, 2016 8:15 AM
To: OST-EVERYONE <OSTEVERYONE@epa.gov>
Subject: FYI: Advocates Cite New Mercury Study To Urge Updated EPA, FDA Fish Guide

FYI. Your colleagues in EAD have been working with FDA on this for quite some time.

Risk Policy Report - 03/22/2016

Advocates Cite New Mercury Study To Urge Updated EPA, FDA Fish Guide

March 21, 2016

The Environmental Working Group is reiterating its call for EPA and the Food and Drug Administration (FDA) to update 2004 guidelines on fish consumption levels, pointing to its new study that concludes pregnant women who follow the

existing federal advice could harm their developing fetuses by consuming fish with high levels of mercury.

The study "U.S. Fish Advice May Expose Babies To Too Much Mercury," which EWG and the Mercury Policy Project released March 16, tested the hair of 254 women living in 40 states for mercury. The researchers found that "almost 30 percent" of these women had mercury levels exceeding an EPA exposure guideline of 1 part per million (ppm) which EWG calls outdated and "associated with clear risks to a developing fetus."

Study author Sonya Lunder, a senior analyst with EWG, said in a March 15 interview with *Inside EPA* that the 1 ppm number is extrapolated from EPA's 2001 reference dose (RfD) for methylmercury. EPA describes the RfD of 1x10^-4 milligrams per kilogram bodyweight per day as the maximum amount that it anticipates an individual can eat daily over a lifetime without experiencing adverse effects.

EPA has placed methylmercury on its most recent list of priority contaminants for the agency's Integrated Risk Information System to re-assess in the next few years.

Lunder and others have questioned EPA's RfD in recent years, pointing to newer studies that indicate the RfD is not protective of fetuses, such as a more recent study by Philippe Grandjean and others suggesting that 0.58 ppm is a more appropriate maximum limit for pregnant women. EWG's new study concludes that "nearly 60 percent" of the women it tested exceeded this more stringent benchmark.

The women were selected because they reported eating 2-3 meals of seafood per week, allowing EWG researchers to approximate conditions if federal fish consumption advice were followed. Both the most recent Dietary Guidelines for Americans (DGA), which the Department of Health and Human Services released in January, and the latest draft of EPA and FDA's joint advisory for pregnant women or those who could become pregnant, released in June 2014, recommend consuming no less than 8 ounces of fish per week and no more than 12 ounces.

Since these amounts are significantly larger than the 3.5 ounces of fish per week that national health surveys have shown the average American eats per week, health advocates have charged that EPA and FDA are seeking to increase women's fish consumption without providing sufficient information on what types of fish they should consume. Different fish species vary widely both in their general levels of mercury and the levels of beneficial oils and fats that they

contain. Advocates in the past have praised the latest DGA for providing species-specific recommendations, while cautioning the DGA doesn't provide sufficient advice on fish species to avoid (*Risk Policy Report*, Jan. 12).

EWG and other stakeholders, ranging from members of Congress to the fishing industry, have been pushing the agencies for several years to update their joint advice, last published in 2004. EWG argues that the advice needs to better identify fish species that are low in mercury and high in the beneficial fats and oils for which fish is recommended, particularly to pregnant women. Lunder and colleagues met with congressional staffers to discuss their findings, and are also seeking to schedule briefings with EPA and FDA staff, she said.

"We wanted to test the new draft advice," Lunder said of the study. "We didn't see any difference in hair mercury levels [in women who ate] two or three meals [of fish per week] versus more. That tells us that the species [of fish eaten] are more important than the amount."

Lunder added the DGA "does exactly what we ask for: name high and low mercury fish. The thing they don't address directly is mercury risk for people who eat fish frequently, and they punt to EPA and FDA."

The agencies' joint advice is also designed specifically for pregnant women or those who could become pregnant, while the DGA is a general advice for the population. Mercury is a potent neurotoxin, particularly for the very young, and it contaminates fish in the form of methylmercury. Seafood poses a challenging risk-benefit tradeoff because beneficial oils and fats in seafood boost brain and eye development in the fetus, making it important for pregnant women to eat. The goal is to eat fish species that provide the least risk and the most benefit.

"Our analysis of the women's dietary surveys found that while only a small amount of their mercury intake came from species the government says to avoid or limit, the great majority of the toxin came from species the government does not warn against, especially tuna steaks and tuna sushi," EWG's study says. "And although the women in our study eat more than twice as much fish as the average American, almost 60 percent still don't get the amount of omega-3s recommended during pregnancy from seafood in their diets."

Further, EWG finds that only slightly more than one-quarter "of our participants had both enough omega-3 intake and mercury levels below the EPA exposure guideline of 1 part per million. About one in six had higher levels of mercury and lower than optimal omega-3s, a particularly unhealthy combination."

The group urges EPA and FDA to update the advisory to "specify the full list of

low mercury-high omega-3 fish, such as salmon, that women should add to their diets. This information is already included in the most recent edition of the [DGA] . . . so aligning the recommendations would provide greater clarity to the government's advice . . . The advice should also educate women about the hazards of mercury and name additional species they should limit or avoid for up to a year before conception, such as seabass, halibut and marlin."

EPA and FDA spokesmen provide little insight on the status of the joint advisory. "The FDA and EPA are revising the draft advice," an EPA spokesman writes Inside EPA. "The draft advice was issued in June 2014 to request public comments and since then, we have received over 200 public comments and held a Risk Communication Advisory Committee Meeting in November 2014. We've taken comments into consideration. Based on this information we will update our advice."

An FDA spokesman provided a duplicate statement.

But health advocates and agency sources indicate that multiple retirements among technical experts and key managers working on the advisory has likely delayed its finalization. Neither agency's spokesman responded to questions about the retirements' affect on the advisory, nor to requests for comment on the EWG report.

The report comes as EPA's Inspector General (IG) is conducting a review of the agency's existing public health communication about mercury contamination in fish, begun last fall. A September memo says the review is a discretionary assignment in the IG's fiscal year 2015 annual plan, and will be conducted within the Office of Water, EPA regions, states and tribes.

"The anticipated benefit of this project is to improve the effectiveness of risk communication efforts to ensure the protection of populations most effected by the consumption of mercury-contaminated fish," the memo says (*Risk Policy Report*, Sept. 15).

An IG spokeswoman says the review "is still at the preliminary research phase . . . [IG] program evaluations and audits that progress beyond preliminary research may eventually entail field work, followed by a reporting phase culminating in a final, public report." -- *Maria Hegstad*

Octavia Conerly

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To: Fleisig, Erica[Fleisig.Erica@epa.gov]; Keating, Jim[Keating.Jim@epa.gov]
Cc: Anderson, Danielle[Anderson.Danielle@epa.gov]; McRae, Evelyn[McRae.Evelyn@epa.gov]
From: Washington, Evelyn
Sent: Mon 10/24/2016 2:00:16 PM
Subject: RE: OD list for National Branch

Sorry it didn't get sent on beyond her. The meeting was/is at 9 every Monday so it didn't make the list.

I will send an email to Betsy asking for her guidance. **Ex. 5 - Deliberative Process** I was out Friday, can you fill me in?

From: Fleisig, Erica
Sent: Monday, October 24, 2016 9:27 AM
To: Keating, Jim <Keating.Jim@epa.gov>; Washington, Evelyn <Washington.Evelyn@epa.gov>
Cc: Anderson, Danielle <Anderson.Danielle@epa.gov>; McRae, Evelyn <McRae.Evelyn@epa.gov>
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Cc: Moore, Keara <Moore.Keara@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wilcut, Lars <Wilcut.Lars@epa.gov>; Vlcan, Manjali <Vlcan.Manjali@epa.gov>
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WQS Roundtable – led by R3

- Topic related to work with DRBC

Shari Z. Barash

Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Washington, Evelyn
Sent: Mon 11/9/2015 4:31:00 PM
Subject: OMB review of fish advice

Just got a quick (maybe incomplete?) message from Sara to let you know when fish advice went to OMB and for how long. I believe it was while I was acting DD, which would have been in 2010. I don't recall how long it was there but believe it was less than 90 days.

Hope this helps and isn't too late.

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Bone, Tracy[Bone.Tracy@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Frey, Sharon[Frey.Sharon@epa.gov]; Kramer, Bill[Kramer.Bill@epa.gov]; Stahl, Leanne[stahl.leanne@epa.gov]; Thalathara, Roselyn[thalathara.roselyn@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Martinez, Menchu[martinez.menchu-c@epa.gov]
Cc: Barash, Shari[Barash.Shari@epa.gov]

Call-in information

Ex. 6 - Personal Privacy

Agenda

•□□□□□□□ WQSMA calls: Shari would like to keep finding topics of interest our team can present on the calls (e.g., organics paper in March, fish advice in May)

•□□□□□□□ Fish advice: working on comments received since advice was released; Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

•□□□□□□□ Region 5 water safety handout: thanks for providing comments

•□□□□□□□ National Park Service signage: provide comments by Thursday

•□□□□□□□ Reminder to use SOPs, especially for info requests (e.g., copy TL on response). Lisa will email the latest version.

•□□□□□□□ ORD meeting on RfD

•□□□□□□□ Fish IG: had questions on Ex. 5 - Deliberative Process

•□□□□□□□ Beach data: still some lagging states (contract or new staffing issues), but Bill has heard from everyone

•□□□□□□□ Verification tool: latest version out for people to use. Updated Access database almost ready to post. Support web page has technical documentation; vT documentation is not up there.

•□□□□□□□ Leanne working with Betsy Southerland on Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

•□□□□□□□ Status briefings next week on fish tissue repository and Vols. 1 & 2. May need to reschedule both.

•□□□□□□□ John has ES&T proof of organics article.

From: Larimer, Lisa
Location: FDA (College Park), Room 2E-032 in the CFSAN Wiley building
Importance: Normal
Subject: 3rd FDA-EPA meeting on fish advice
Start Date/Time: Wed 4/22/2015 12:30:00 PM
End Date/Time: Wed 4/22/2015 4:30:00 PM

Ex. 5 - Deliberative Process

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Bone, Tracy[Bone.Tracy@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Kramer, Bill[Kramer.Bill@epa.gov]; Stahl, Leanne[stahl.leanne@epa.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Barash, Shari[Barash.Shari@epa.gov]; Frey, Sharon[Frey.Sharon@epa.gov]

Room change! Now in Rock Creek (E)
Draft agenda

- Fish program newsletter: Ex. 5 - Deliberative Process
- Ex. 5 - Deliberative Process
- EWG visit with ORD on fish advice [Lisa]
  Ex. 5 - Deliberative Process
- Sanitary survey app update [Sam]
  Ex. 5 - Deliberative Process
- Beach conference proceedings [Tracy]
  Decision: Drop the author & presenter names from list of posters.
- Ex. 5 - Deliberative Process
- Ex. 5 - Deliberative Process

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Bone, Tracy[Bone.Tracy@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Kramer, Bill[Kramer.Bill@epa.gov]; Stahl, Leanne[stahl.leanne@epa.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Barash, Shari[Barash.Shari@epa.gov]; Frey, Sharon[Frey.Sharon@epa.gov]; Moore, Keara[Moore.Keara@epa.gov]; Thalathara, Roselyn[thalathara.roselyn@epa.gov]

Agenda & notes

Retreat date - 11/17. Requests for advance interviews coming today or tomorrow.
Fish newsletter - microplastics issue - needs DD/DDD review by next Wed
ORD request to use 2008-09 fish data - ok to use in site-specific sense? Look at data as normal distribution to see if hot spots associated with Superfund sites are statistically different.
Beach documentation updates - 3 new documents posted. New BEACON update in place this week (est), then new schema will be posted on our website.
Verification tool - NCC meeting this week. Asked for waiver from agency web standards. Had to update certification for system (last done in 2011). [Does Betsy still need to send waiver email? Bill will contact PMO person.]
Shellfish/HABs - Chart with cumulative advisories due to HABs on West coast from NOAA. On east coast, all of northeast is shut down. Lots of articles recently.
QA - Bill will be out of the office next week, along with all QA people.
Fish advice - Meetings with Children's Health Protection and ORD Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

MOU with FDA - past collaboration on shellfish (see ISSC list), phage (Sharon), mercury fish advice

Ex. 5 - Deliberative Process

Travel budget - Input due this Friday.
NHANES special study - Proposal was submitted on 9/30. Will hear back in December whether NHANES accepted the proposal.
NWIFC meeting - Sam working with Lon on date. Need to discuss internally before the meeting.
CR prioritization - Get requests of immediately needed funds to Lisa.

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Sent: Fri 10/23/2015 2:39:48 PM
Subject: FW: EPA OIG investigation on contaminants in seafood

Did you have a conv. w/Sharon on this?

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Friday, October 23, 2015 8:19 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Subject: Re: EPA OIG investigation on contaminants in seafood

Thanks Betsy. Just wanted to see what your thoughts were regarding EWG's request that until the OIG's report is completed, we not finalize the advice.

Sent from my BlackBerry 10 smartphone.

From: Southerland, Elizabeth

Sent: Thursday, October 22, 2015 4:57 PM

To: Natanblut, Sharon; Larimer, Lisa; Wathen, John

Cc: Hisel-Mccoy, Sara

Subject: RE: EPA OIG investigation on contaminants in seafood

The meetings we have had with the OIG have all focused on EPA's work on the state fish consumption advisories, not on the joint FDA EPA advice. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, October 22, 2015 1:26 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: FW: EPA OIG investigation on contaminants in seafood

Hi there,

Just heard about this and was hoping we could find a time to discuss.

Thanks.

Sharon

From: Natanblut, Sharon
Sent: Thursday, October 22, 2015 1:25 PM
To: Sharp, Jeremy; Kux, Leslie
Cc: Boon, Caitlin; McKinnon, Robin; Cristinzio, Dayle; Pillsbury, Laura; Saben, Alyson L; Bernard, Susan; Mayne, Susan; Harper, Kristina; Taylor, Michael R
Subject: RE: EPA OIG investigation on contaminants in seafood

FYI

From: Sonya Lunder [mailto:sonya@ewg.org]
Sent: Thursday, October 22, 2015 12:09 PM
To: Natanblut, Sharon
Subject: EPA OIG investigation on contaminants in seafood

Sharon,

Here is the EPA OIG notice about its investigation into contaminant warnings by EPA's Office of Water. As I also mentioned today, EWG is planning to formally ask EPA and FDA to hold of on finalizing the draft seafood advice while this investigation is pending. We believe the draft advice is not health protective, as detailed in our public comments to FDA. We have provided OIG with model advice from state governments that is more comprehensive and nuanced, as a model for the federal agencies to employ when advising pregnant women and parents.

Thanks for forwarding this information to the scientists in charge of mercury issues. I would be eager to speak with them about the Agency's plans to incorporate public comments and update the draft advice.

- Sonya

Sonya Lunder, MPH

Environmental Working Group

Washington DC 20009

Sonya@ewg.org

202/939-9129

From: Wathen, John
Location: DCRoomARN3530CFTB/DC-Ariel-Rios-AO
Importance: Normal
Subject: Fw: FDA-EPA Fish Advice
Start Date/Time: Tue 9/22/2015 3:00:00 PM
End Date/Time: Tue 9/22/2015 3:45:00 PM
Briefing Memo FDA-EPA fish advice.docx

.....
;;;;;

Lisa-

You got this?

~John

From: Schoeny, Rita on behalf of Meiburg, Stan
Sent: Wednesday, September 16, 2015 2:38 PM
To: Wathen, John; Hisel-Mccoy, Sara
Subject: FW: FDA-EPA Fish Advice
When: Tuesday, September 22, 2015 11:00 AM-11:45 AM.
Where: DCRoomARN3530CFTB/DC-Ariel-Rios-AO
Hi, folks. This is on Tom Burke's calendar, and I spent some time with him and Bob Kavlock going over the old, the new and everything in-between. Would you send me the latest materials that you plan to use for DA? I think Tom will be working from home on all the Pope days, so I would like to get him the info beforehand. I plan on being at the meeting – unless we all get caught in the rush.
Thanks.
Rita Schoeny, Ph.D.
Senior Science Advisor, Office of Science Policy
Office of Research and Development
U.S. Environmental Protection Agency
Room 51134 RRB
1200 Pennsylvania Avenue NW (8104R)
Washington DC 20460-0001

202-566-1127
202-565-2911 fax

Address for delivery:
1300 Pennsylvania Ave. NW
Room# 51134 MC8104R
Washington DC 20004
-----Original Appointment-----
From: Meiburg, Stan
Sent: Thursday, September 10, 2015 10:21 AM
To: Meiburg, Stan; Larimer, Lisa; Wathen, John; Hisel-Mccoy, Sara; Southerland, Elizabeth; Kopocis, Ken; Gilinsky, Ellen; Burke, Thomas; Etzel, Ruth; Coopwood, Theodore; Mitchell, Stacey; Schroer, Lee; Klasen,

Matthew; Ingram, Amir
Cc: Loop, Travis; Lalley, Cara; Kavlock, Robert; Hauchman, Fred; Schoeny, Rita; Reed, Khesha; Firestone, Michael; Penman, Crystal; Gentry, Nathan; Foos, Brenda; Conerly, Octavia
Subject: FDA-EPA Fish Advice
When: Tuesday, September 22, 2015 11:00 AM-11:45 AM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomARN3530CFTB/DC-Ariel-Rios-AO
Point of Contact for the Meeting: Lisa Larimer 566-1017
SCt: Denise Anderson, 564-1782

Ex. 6 - Personal Privacy

Purpose: Share the final joint FDA-EPA fish advice with EPA senior leadership. HHS senior leadership is receiving a comparable briefing. The workgroup's goal is to announce the advice in September/October 2015, contingent upon timing of review by HHS and OMB.
Background: An FDA-EPA workgroup has developed an update to the March 2004 fish advisory on mercury in fish and shellfish. The advice recommends consumption frequencies for the target audience of pregnant and breastfeeding women, women who could become pregnant, and children.
Last possible date for the meeting: After 9/9/15 and before 9/25/15
EPA Staff (Required): OW: Lisa Larimer, John Wathen, Sara Hisel-McCoy, Elizabeth Southerland, Ken Kopocis, Ellen Gilinsky
ORD: Thomas Burke
OA: Ruth Etzel, Theodore Coopwood
OGC: Stacey Mitchell, Lee Schroer
EPA Staff (Optional): OW: Travis Loop, Cara Lalley
ORD: Robert Kavlock, Fred Hauchman, Rita Schoeny
OA: Khesha Reed, Michael Firestone

Cc: Larimer, Lisa[Larimer.Lisa@epa.gov]
To: Barash, Shari[Barash.Shari@epa.gov]
From: Wathen, John
Sent: Fri 8/28/2015 3:26:40 PM
Subject: Re: Meeting request materials for fish advice

That's kind of a good dynamic, Shari. With three people involved , you

---

From: Barash, Shari
Sent: Friday, August 28, 2015 11:25 AM
To: Wathen, John; Conerly, Octavia; Bethel, Heidi
Cc: Larimer, Lisa
Subject: RE: Meeting request materials for fish advice

I will be in except for 9/4.

Shari Z. Barash

Acting Chief

National Water Quality Standards Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Wathen, John
Sent: Friday, August 28, 2015 11:24 AM
To: Conerly, Octavia; Bethel, Heidi
Cc: Barash, Shari; Larimer, Lisa
Subject: Re: Meeting request materials for fish advice

Octavia, Heidi-

I will be in the office Mon-Wed if you have any questions about this. After that, I will be out 9/3-9/9. I believe Lisa will be back in on 9/9.

~John

From: Larimer, Lisa
Sent: Friday, August 28, 2015 10:26 AM
To: Barash, Shari
Cc: Wathen, John
Subject: Fw: Meeting request materials for fish advice

Octavia, Heidi and Matt were all out of the office, but Heidi was checking email and sent the stuff to Crystal to process and forwarded to Lynn while Octavia is out. Making sure you two have the materials in case anything comes up. Will probably be offline for most of the rest of the day now. See you in September!

-Lisa

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 5:35 PM
To: Bethel, Heidi; Conerly, Octavia; Klasen, Matthew
Subject: Meeting request materials for fish advice

We finally met with HHS and USDA on the confluence of our fish advice with their Dietary Guidelines for Americans and we are good to go. Here are the meeting request and memo for the briefing for the Administrator.

FYI, I won't be in the office tomorrow through Labor Day. John will be in the office tomorrow morning, but then out until Sept. 10. Hopefully you won't have any questions. If you do and can't reach us, try Samantha Fontenelle.

Thanks!

Lisa

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Fri 5/1/2015 5:36:32 PM
Subject: Re: list of fish to add to the Advice - from public comments

I plead guilty

From: Larimer, Lisa
Sent: Friday, May 1, 2015 9:45 AM
To: Wathen, John; Naidenko, Olga
Subject: RE: list of fish to add to the Advice - from public comments

John,

I think there may be some confusion here. Olga is trying to come up with names of fish that people specifically asked about in comments that we do not have in our table already (e.g., mahi

Ex. 5 - Deliberative Process

please let me know. Ex. 6 - Personal Privacy

From: Wathen, John
Sent: Friday, May 01, 2015 9:20 AM
To: Naidenko, Olga
Cc: Larimer, Lisa
Subject: Re: list of fish to add to the Advice - from public comments

Olga-

We have a few additional lists of fish, **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

I will discuss this next week with you.

~John

From: Naidenko, Olga
Sent: Thursday, April 30, 2015 1:12 PM
To: Wathen, John
Cc: Larimer, Lisa
Subject: list of fish to add to the Advice - from public comments

Hello John,

I am helping Lisa with proofing the data table for the Fish Advice. Question - how can I make a list of additional fish that the commenters asked FDA/EPA to add? Maybe we already have such a list? Or how can I access the comments to compile it?

Thank you!

Olga

Olga V. Naidenko, PhD

AAAS Fellow 2014-2015

Assigned to the U.S. EPA

Office of Water

Office of Science and Technology

Standards & Health Protection Division

202-566-0203

To: Robiou, Grace[Robiou.Grace@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Naidenko, Olga[Naidenko.Olga@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Carrington, Clark D[Clark.Carrington@fda.hhs.gov]; 'Natanblut, Sharon'[Sharon.Natanblut@fda.hhs.gov]; 'William.jones@fda.hhs.gov'['William.jones@fda.hhs.gov']; 'Deborah.smegal@fda.hhs.gov'['Deborah.smegal@fda.hhs.gov']; 'Elkin, Ted'[Ted.Elkin@fda.hhs.gov]
From: Wathen, John
Sent: Fri 4/10/2015 3:14:35 PM
Subject: Info for Second FDA-EPA Meeting on Fish Advice

From: Robiou, Grace
Sent: Tuesday, March 17, 2015 3:31 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Larimer, Lisa; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: Second FDA-EPA Meeting on Fish Advice
When: Tuesday, April 14, 2015 9:00 AM-4:00 PM.
Where: DCRoomWest6105AAssateague/DC-EPA-West-OST

To: Hisel-Mccoy, Sara[Hisel-McCoy.Sara@epa.gov]; Robiou, Grace[Robiou.Grace@epa.gov]; Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
Sent: Wed 3/18/2015 1:13:26 PM
Subject: FW: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Wednesday, March 18, 2015 9:07 AM
To: Wathen, John
Subject: Re: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.

It was remarkable. What a pleasure working with all of you.

Sharon

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Tuesday, March 17, 2015 03:51 PM
To: Natanblut, Sharon
Subject: RE: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.

Thanks very much, Sharon. Enjoyed our productive day.

~John

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, March 17, 2015 3:04 PM
To: Wathen, John
Subject: Fw: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.

From: Bravo, Luis
Sent: Tuesday, March 17, 2015 01:57 PM
To: Natanblut, Sharon
Cc: Sepe, Daniel
Subject: RE: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.

Here is the PowerPoint.

R/ Luis

From: Natanblut, Sharon
Sent: Tuesday, March 17, 2015 1:47 PM
To: Bravo, Luis
Cc: Sepe, Daniel
Subject: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
Cc: Jones, William[William.Jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Natanblut, Sharon
Sent: Wed 10/7/2015 10:58:48 PM
Subject: Response to HHS comments 10.07.15.docx
Response to HHS comments 10.07.15.docx

Hi there,

I didn't complete this – it looks great – but I had some edits. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Thanks.

Sharon

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
Cc: Jones, William[William.Jones@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Natanblut, Sharon
Sent: Wed 10/7/2015 10:34:48 PM
Subject: Fish Advice Qs and As-10.7.15.docx
Fish Advice Qs and As-10.7.15.docx

You've done such a great job. I added some suggested edits/comments for consideration.

Thanks so much.

Sharon

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Jones, William[William.Jones@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Smegal, Deborah
Sent: Thur 9/10/2015 5:27:07 PM
Subject: RE: latest versions of fish advice documents
FISH_CHART_V_9.2.pdf

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, September 10, 2015 1:07 PM
To: Smegal, Deborah; Jones, William; Natanblut, Sharon; Wathen, John
Subject: RE: latest versions of fish advice documents

Oops, sorry I meant vertical.

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Wednesday, September 09, 2015 1:02 PM
To: Larimer, Lisa; Jones, William; Natanblut, Sharon; Wathen, John
Subject: RE: latest versions of fish advice documents

Here it is.

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, September 09, 2015 12:27 PM
To: Smegal, Deborah; Jones, William; Natanblut, Sharon; Wathen, John
Subject: RE: latest versions of fish advice documents

I will. Is there a new horizontal version of the chart?

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Tuesday, September 08, 2015 10:51 AM
To: Jones, William; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Subject: latest versions of fish advice documents

Hi,

Here are the latest versions, that include the updated fish chart from last week. Lisa can you please make sure these get into the EPA/FDA sharepoint directory?

Thanks

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Jones, William[William.Jones@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Smegal, Deborah
Sent: Wed 9/9/2015 5:02:19 PM
Subject: RE: latest versions of fish advice documents
FISH_CHART_H_9.2.pdf

Here it is.

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, September 09, 2015 12:27 PM
To: Smegal, Deborah; Jones, William; Natanblut, Sharon; Wathen, John
Subject: RE: latest versions of fish advice documents

I will. Is there a new horizontal version of the chart?

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Tuesday, September 08, 2015 10:51 AM
To: Jones, William; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Subject: latest versions of fish advice documents

Hi,

Here are the latest versions, that include the updated fish chart from last week. Lisa can you please make sure these get into the EPA/FDA sharepoint directory?

Thanks

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Jones, William[William.Jones@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Smegal, Deborah
Sent: Tue 9/8/2015 2:51:13 PM
Subject: latest versions of fish advice documents
FISH_CHART_H_9.2.pdf
Fish Advice Qs and As-8 20 15_V. 2 clean.docx
technical web page-fish advice-08 20 15_V.2 (2).docx
Fish Advice Qs and As-8 24 15 clean with comment box for NIH and placeholder for diagram.docx
FRDTS#2015-646-draft FR notice-fish consumption advice revised version 8 24 2015 clean.docx
Summary Table of Response to Public comments 8 24 15 clean w.comment box for NIH.2.docx

Hi,

Here are the latest versions, that include the updated fish chart from last week. Lisa can you please make sure these get into the EPA/FDA sharepoint directory?

Thanks

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Natanblut, Sharon
Sent: Tue 9/1/2015 8:01:14 PM
Subject: RE: fish advice -- possible revision

Great! EPA?

From: Smegal, Deborah
Sent: Tuesday, September 01, 2015 3:52 PM
To: Natanblut, Sharon; Jones, William; Larimer, Lisa; Wathen, John
Subject: RE: fish advice -- possible revision

Looks good to me.

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Natanblut, Sharon
Sent: Tuesday, September 01, 2015 3:49 PM
To: Jones, William; Smegal, Deborah; Larimer, Lisa; Wathen, John
Subject: FW: fish advice -- possible revision
Importance: High

Hi guys,

I thought our call with the Dietary Guidelines folks went beautifully. The one point that they raised, that I think we may need to address is that **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process It's really in the QA that we explain that better.

So, I asked our designer to Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process So, what do you think? If you guys like it, I think we could show it to Kelly at HHS to see if that addresses their concern, and if it does, then we could send this version in place of the other forward for formal HHS clearance.

Any chance you could comment today or early tomorrow? Soon I'll be leaving for Asia and I would like to move things forward as best I can beforehand.

Thanks.

Sharon

To: Jones, William[William.Jones@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Natanblut, Sharon
Sent: Tue 9/1/2015 7:58:10 PM
Subject: RE: fish advice -- possible revision

Thanks Bill. Others?

From: Jones, William
Sent: Tuesday, September 01, 2015 3:58 PM
To: Natanblut, Sharon; Smegal, Deborah; Larimer, Lisa; Wathen, John
Subject: RE: fish advice -- possible revision

I think that is a clarifying improvement, and I like it.

From: Natanblut, Sharon
Sent: Tuesday, September 01, 2015 3:49 PM
To: Jones, William; Smegal, Deborah; Larimer, Lisa; Wathen, John
Subject: FW: fish advice -- possible revision
Importance: High

Hi guys,

I thought our call with the Dietary Guidelines folks went beautifully. The one point that they raised, that I think we may need to address is that the chart itself does not make clear that Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process It's really in the QA that we explain that better.

So, I asked our designer to **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process So, what do you think? If you guys like it, I think we could show it to Kelly at HHS to see if that addresses their concern, and if it does, then we could send this version in place of the other forward for formal HHS clearance.

Any chance you could comment today or early tomorrow? Soon I'll be leaving for Asia and I would like to move things forward as best I can beforehand.

Thanks.

Sharon

To: Wathen, John[Wathen.John@epa.gov]
From: Barash, Shari
Sent: Fri 8/28/2015 6:27:17 PM
Subject: RE: General Ruminations

Yes, agreed.

Shari Z. Barash

Acting Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Wathen, John
Sent: Friday, August 28, 2015 2:20 PM
To: Barash, Shari
Subject: Re: General Ruminations

Yes I thinkit turned out well too and I'm not unhappy about it. As you suggest, we will hopefully get more efficient with time. At our best, Denise and I would either write and the other edit, then the writer check. At the worst, Denise would write, I would check, then she would rewrite what she damn well please and had no one check. Sometimes that did not turn out well.

We have a different sit., because both of have technical sense, but everyone needs a check. The most important thing I learned in grad school was being good about taking editing. None of us is Earnest Hemingway, but even the best writers have editors.

~John

From: Barash, Shari
Sent: Friday, August 28, 2015 11:47 AM
To: Wathen, John
Cc: Larimer, Lisa
Subject: RE: General Ruminations

Thanks for the thoughts. I am totally open to feedback on how we can make it go smoothly and with less iterations (although I think the FL thing turned out well, so maybe it went ok). In general, Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Shari Z. Barash

Acting Chief

National Water Quality Standards Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Wathen, John
Sent: Friday, August 28, 2015 11:43 AM
To: Barash, Shari
Cc: Larimer, Lisa
Subject: General Ruminations

Did this send a minute ago? Anyway, I was saying that it is a pretty good dynamic when you can have three people covering something. I was reminded on the FL document that we all have some getting used to each other's working, communicating, writing, and editing styles to do. I Ex. 6 - Personal Privacy

Ex. 6 - Personal Privacy

Ex. 6 - Personal Privacy

Thank goodness my next major task is one that I am only about 6 months behind on thanks to my acting stint and other tasks. I have the NRSA organics paper to write w Ex. 5 - Deliberative Process but I have a good solid month of work to do on it before the end of the year. Good luck says I .

Have a good weekend

~John

From: Barash, Shari
Sent: Friday, August 28, 2015 11:25 AM
To: Wathen, John; Conerly, Octavia; Bethel, Heidi
Cc: Larimer, Lisa
Subject: RE: Meeting request materials for fish advice

I will be in except for 9/4.

Shari Z. Barash

Acting Chief

National Water Quality Standards Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Wathen, John
Sent: Friday, August 28, 2015 11:24 AM
To: Conerly, Octavia; Bethel, Heidi
Cc: Barash, Shari; Larimer, Lisa
Subject: Re: Meeting request materials for fish advice

Octavia, Heidi-

I will be in the office Mon-Wed if you have any questions about this. After that, I will be out 9/3-9/9. I believe Lisa will be back in on 9/9.

~John

From: Larimer, Lisa
Sent: Friday, August 28, 2015 10:26 AM
To: Barash, Shari
Cc: Wathen, John
Subject: Fw: Meeting request materials for fish advice

Octavia, Heidi and Matt were all out of the office, but Heidi was checking email and sent the stuff to Crystal to process and forwarded to Lynn while Octavia is out. Making sure

you two have the materials in case anything comes up. Will probably be offline for most of the rest of the day now. See you in September!

-Lisa

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 5:35 PM
To: Bethel, Heidi; Conerly, Octavia; Klasen, Matthew
Subject: Meeting request materials for fish advice

We finally met with HHS and USDA Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process and we are good to go. Here are the meeting request and memo for the briefing for the Administrator.

FYI, I won't be in the office tomorrow through Labor Day. John will be in the office tomorrow morning, but then out until Sept. 10. Hopefully you won't have any questions. If you do and can't reach us, try Samantha Fontenelle.

Thanks!

Lisa

To: Wathen, John[Wathen.John@epa.gov]
From: Axie N.
Sent: Wed 1/18/2017 9:48:10 PM
Subject: Re: POSTED LIVE: EPA and FDA Fish Advice

BRAVO! Wow, at long last□

Sent from my iPad

On Jan 18, 2017, at 9:42 AM, Wathen, John <Wathen.John@epa.gov> wrote:

> Well, if anyone is curious about what exactly it is that I do, this is one thing I have been working on for about 8 years.
>
> ~John, ancient father or whatever
>
> **From:** Kearney, Renee
> **Sent:** Wednesday, January 18, 2017 9:28 AM
> **To:** Lalley, Cara <Lalley.Cara@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
> **Cc:** Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
> **Subject:** POSTED LIVE: EPA and FDA Fish Advice
>
> **Per your request – DONE**
>
> **https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish**
>
> ---
>
> ***Renee Kearney***, Webmaster
>
> 202-564-8076 (Office)

202-281-0176 (Work Cell)

Smile to brighten somebody's day

Help to touch somebody's heart

From: Lalley, Cara
Sent: Wednesday, January 18, 2017 8:52 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Kearney, Renee <Kearney.Renee@epa.gov>
Subject: FW: Media Relations is sending this release at 9:15 AM: EPA and FDA Issue Final Fish Consumption Advice

Here is the final press release; sorry, but it appears I could not convince them to add a separate web link at the end to EPA's main fish webpage (but readers can get to us via the advice chart and FDA's webpages).

Renee- please start making all of our pages live now. I'll send you the link for the EPA press release when I see it appear in the newsroom.

From: Dennis, Allison
Sent: Wednesday, January 18, 2017 8:48 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Subject: Fwd: Media Relations is sending this release at 9:15 AM: EPA and FDA Issue Final Fish Consumption Advice

Sent from my iPhone

Begin forwarded message:

From: "Valentine, Julia" <Valentine.Julia@epa.gov>
Date: January 18, 2017 at 8:16:34 AM EST

To: AO OPA OMR 60 Minute Warning
<AO_OPA_OMR_60_Minute_Warning@epa.gov>
Cc: "Loop, Travis" <Loop.Travis@epa.gov>, "Dennis, Allison"
<Dennis.Allison@epa.gov>, "Fuld, John" <Fuld.John@epa.gov>
Subject: Media Relations is sending this release at 9:15 AM: EPA and FDA Issue Final Fish Consumption Advice

CONTACTS:

Enesta Jones

EPA

jones.enesta@epa.gov

(202) 236-2426

Theresa Eisenman

FDA

theresa.eisenman@fda.hhs.gov

(301) 796-2969

Consumer Inquiries: 888-INFO-FDA

FOR IMMEDIATE RELEASE
January 18, 2017

EPA and FDA Issue Final Fish Consumption Advice

Chart makes it easier than ever for pregnant women and others to choose from dozens of healthy and safe options; nearly 90 percent of fish eaten in the U.S. fall into "best choices" category

WASHINGTON - Today, the U.S. Environmental Protection Agency and the U.S. Food and Drug Administration issued final advice regarding fish consumption. This advice is geared toward helping women who are pregnant or may become pregnant – as well as breastfeeding mothers and parents of young children – make informed choices when it comes to fish that are healthy and safe to eat. (This advice refers to fish and shellfish collectively as "fish.")

To help these consumers more easily understand the types of fish to select, the agencies have created an easy-to-use reference chart that sorts 62 types of fish into three categories:

--"Best choices" (eat two to three servings a week)

--"Good choices" (eat one serving a week)

--"Fish to avoid"

Fish in the "best choices" category make up nearly 90 percent of fish eaten in the United States.

An FDA analysis of fish consumption data found that 50 percent of pregnant women surveyed ate fewer than 2 ounces a week, far less than the amount recommended. Because the nutritional benefits of eating fish are important for growth and development during pregnancy and early childhood, the agencies are advising and promoting a minimum level of fish consumption for these groups. The advice recommends 2-3 servings of lower-mercury fish per week, or 8 to 12 ounces. However, all fish contain at least traces of mercury, which can be harmful to the brain and nervous system if a person is exposed to too much of it over time. The maximum level of consumption recommended in the final advice is consistent with the previous recommended level of 12 ounces per week. The new advice is consistent with the 2015 - 2020 Dietary Guidelines for Americans.

For adults, a typical serving is 4 ounces of fish, measured before cooking. Serving sizes for children should be smaller and adjusted for their age and total calorie needs. It is recommended that children eat fish once or twice a week, selected from a variety of fish types.

"Fish are an important source of protein and other nutrients for young children and women who are or may become pregnant, or are breastfeeding. This advice clearly shows the great diversity of fish in the U.S. market that they can consume safely," said FDA Deputy Commissioner for Foods and Veterinary Medicine Stephen Ostroff, M.D. "This new, clear and

concrete advice is an excellent tool for making safe and healthy choices when buying fish." Choices lower in mercury include some of the most commonly eaten fish, such as shrimp, pollock, salmon, canned light tuna, tilapia, catfish and cod.

When updating the advice, the agencies took a cautious and highly protective approach to allow consumers to enjoy the benefits of fish while avoiding those with higher levels of mercury, which is especially important during pregnancy and early childhood. The average mercury content of each type of fish was calculated based on FDA data and information from other sources. The updated advice cautions parents of young children and certain women to avoid seven types of fish that typically have higher mercury levels: tilefish from the Gulf of Mexico; shark; swordfish; orange roughy; bigeye tuna; marlin; and king mackerel.

For fish caught recreationally, consumers are urged to check for local advisories where they are fishing and gauge their fish consumption based on any local and state advisories for those waters. If no information on fishing advisories is available, eat just one fish meal a week from local waters and also, avoid other fish that week. Consumers should clean and trim the fish they catch of fat and skin, since locally-caught fish may contain contaminants besides mercury that can be reduced by proper trimming and cooking, (e.g. broiling instead of frying can reduce some contaminants by letting fat drip away from the fish).

"It's all about eating and enjoying fish of the right kind and in the right amounts," said EPA Director for Water Science and Technology, Elizabeth Southerland, Ph.D. "This joint advice not only provides information for fish consumers who buy from local markets, but it also contains good information for people who catch their own fish or are provided fish caught by friends or relatives."

All retailers, grocers and others are urged to post this new advice, including the reference chart listing fish to choose, prominently in their stores so consumers can make informed decisions when and where they purchase fish. The agencies will be implementing a consumer education campaign working with a wide array of public and private partners featuring the new advice.

In June 2014, the agencies issued draft advice which encouraged pregnant women and others to eat between 8 and 12 ounces of fish a week of fish "lower in mercury" but did not provide a list showing consumers which fish are lower in mercury. The advice issued today also takes into account more than 220 comments received from academia, industry, nongovernmental organizations and consumers as well as an external peer review of the information and method used to categorize the fish.

For More Information:

•□□□□□□□□ Eating Fish: What Pregnant Women and Parents Should Know: http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm393070.htm

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

The EPA, a federal agency, works to protect all Americans from significant risks to human health and the environment where they live, learn and work. The agency focuses on all parts of society, from individuals to businesses and local governments. It develops regulations concerning natural resources, energy, transportation, agriculture, and industry and supports the various facets of environmental research and protection.

R017

Julia P. Valentine

Acting Director

Office of Media Relations

US EPA Headquarters

202.564.2663 desk

202.740.1336 m/txt

To: Barash, Shari[Barash.Shari@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Hisel-Mccoy, Sara
Sent: Wed 1/18/2017 9:47:22 PM
Subject: FW: Shout Outs - Do we have anything canned for the HG fish advice?

From: Conerly, Octavia
Sent: Wednesday, January 18, 2017 3:51 PM
To: Flaherty, Colleen <Flaherty.Colleen@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Washington, Evelyn <Washington.Evelyn@epa.gov>
Subject: FW: Shout Outs

Good afternoon,

Please prepare a 'shout-out' for OW to send out regarding the fish advice and the HHBPs. John would like our write-ups by 9am tomorrow morning. So please send them to me by 8am tomorrow morning.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4301T

Room 5233U

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Fuld, John
Sent: Wednesday, January 18, 2017 11:48 AM
To: Gonzalez, Yvonne V. <Gonzalez.Yvonne@epa.gov>; Harris, Adrienne <Harris.Adrienne@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>; Nandi, Romell <Nandi.Romell@epa.gov>; Farris, Erika D. <Farris.Erika@epa.gov>
Cc: Lousberg, Macara <Lousberg.Macara@epa.gov>; Stevens, Robert <Stevens.Robert@epa.gov>; Fontaine, Tim <Fontaine.Tim@epa.gov>
Subject: RE: Shout Outs

Also may help with everything going on. We have had some statements this week which a lot of folks worked on in your areas.

1/17- Compendium of State Approaches for Manure Management (Statement)

1/17- Human Health Benchmarks for Pesticides (Statement)

1/17-State Water Agency Practices for Climate Change Adaptation_Database Update (Statement)

1/18- Guidance for Building Field Capabilities to Respond to Drinking Water Contamination (Statement)

1/18-Sampling Guidance for Unknown Contaminants in Drinking Water- Update (Statement)

1/18-Ground Water Video Contest Launch (Statement)

1/18- FDA-EPA Final Fish Consumption Advice Announcement (Press Release)

1/18 or 1/19- Aquifer Exemption Geoplatform Map Release (Statement)

From: Fuld, John
Sent: Wednesday, January 18, 2017 11:31 AM
To: Gonzalez, Yvonne V. <Gonzalez.Yvonne@epa.gov>; Harris, Adrienne <Harris.Adrienne@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>; Nandi, Romell <Nandi.Romell@epa.gov>; Farris, Erika D. <Farris.Erika@epa.gov>
Cc: Loop, Travis <Loop.Travis@epa.gov>
Subject: Shout Outs

Team,

Please have your shout outs to me by **Thursday Morning 9 am** as Friday is a Admin holiday.

John W. Fuld, Ph.D.

Media Relations Manager-Water
Environmental Protection Agency

1200 Constitution Ave

Washington DC 20460

Office: 202-564-8847

Cell: 202-815-6408

Fuld.john@epa.gov

To: Frey, Sharon[Frey.Sharon@epa.gov]; Bone, Tracy[Bone.Tracy@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Kramer, Bill[Kramer.Bill@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Moore, Keara[Moore.Keara@epa.gov]; Stahl, Leanne[stahl.leanne@epa.gov]; Thalathara, Roselyn[thalathara.roselyn@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Barash, Shari
Sent: Wed 1/18/2017 9:13:30 PM
Subject: RE: Call for National Fish Call agenda items

The new Fish Advice!!

Shari Z. Barash

Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Frey, Sharon
Sent: Wednesday, January 18, 2017 4:12 PM
To: Barash, Shari <Barash.Shari@epa.gov>; Bone, Tracy <Bone.Tracy@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>; Frey, Sharon <Frey.Sharon@epa.gov>; Kramer, Bill <Kramer.Bill@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Moore, Keara <Moore.Keara@epa.gov>; Stahl, Leanne <stahl.leanne@epa.gov>; Thalathara, Roselyn <thalathara.roselyn@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Call for National Fish Call agenda items

Please send me your proposed agenda items by COB next Wednesday, January 25th. I'm sending a similar email to the states.

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

To: Wathen, John[Wathen.John@epa.gov]
From: Sunderland, Elsie M
Sent: Wed 1/18/2017 4:18:48 PM
Subject: Re: POSTED LIVE: EPA and FDA Fish Advice

Thanks for the update John - hope all is well with you!
Best wishes,
Elsie

Elsie M. Sunderland | Thomas D. Cabot Associate Professor

Harvard John A. Paulson School of Engineering and Applied Sciences
Harvard T.H. Chan School of Public Health
Harvard University, Pierce Hall 127
29 Oxford Street, Cambridge MA 02138 USA

Email: ems@seas.harvard.edu | Tel: +1-617-496-0858 | Web: http://bgc.seas.harvard.edu

On Jan 18, 2017, at 10:18 AM, Wathen, John <Wathen.John@epa.gov> wrote:

Elsie-

You may have inferred what I was up to when I sought your assistance a time or two, but I thought you would appreciate seeing our final output on this. Your work on describing sources of exposure was highly influential here and I think I have mentioned appreciating you Pacific modeling and description of water-column Hg methylation.

Thanks!

~John

https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish

FOR IMMEDIATE RELEASE
January 18, 2017

EPA and FDA Issue Final Fish Consumption Advice

Chart makes it easier than ever for pregnant women and others to choose from dozens of healthy and safe options; nearly 90 percent of fish eaten in the U.S. fall into "best choices" category

WASHINGTON - Today, the U.S. Environmental Protection Agency and the U.S. Food and Drug Administration issued final advice regarding fish consumption. This advice is geared toward helping women who are pregnant or may become pregnant – as well as breastfeeding mothers and parents of young children – make informed choices when it comes to fish that are healthy and safe to eat. (This advice refers to fish and shellfish collectively as "fish.")

To help these consumers more easily understand the types of fish to select, the agencies have created an easy-to-use reference chart that sorts 62 types of fish into three categories:

--"Best choices" (eat two to three servings a week)
--"Good choices" (eat one serving a week)
--"Fish to avoid"

Fish in the "best choices" category make up nearly 90 percent of fish eaten in the United States.

An FDA analysis of fish consumption data found that 50 percent of pregnant women surveyed ate fewer than 2 ounces a week, far less than the amount recommended. Because the nutritional benefits of eating fish are important for growth and development during pregnancy and early childhood, the agencies are advising and promoting a minimum level of fish consumption for these groups. The advice recommends 2-3 servings of lower-mercury fish per week, or 8 to 12 ounces. However, all fish contain at least traces of mercury, which can be harmful to the brain and nervous system if a person is exposed to too much of it over time. The maximum level of consumption recommended in the final advice is consistent with the previous recommended level of 12 ounces per week. The new advice is consistent with the 2015 - 2020 Dietary Guidelines for Americans.

For adults, a typical serving is 4 ounces of fish, measured before cooking. Serving sizes for children should be smaller and adjusted for their age and total calorie needs. It is recommended that children eat fish once or twice a week, selected from a variety of fish types.

"Fish are an important source of protein and other nutrients for young children and women who are or may become pregnant, or are breastfeeding. This advice clearly shows the great diversity of fish in the U.S. market that they can consume safely," said FDA Deputy Commissioner for Foods and Veterinary Medicine Stephen Ostroff, M.D. "This new, clear and concrete advice is an excellent tool for making safe and healthy choices when buying fish." Choices lower in mercury include some of the most commonly eaten fish, such as shrimp, pollock, salmon, canned light tuna, tilapia, catfish and cod.

When updating the advice, the agencies took a cautious and highly protective approach to allow consumers to enjoy the benefits of fish while avoiding those with higher levels of mercury, which is especially important during pregnancy and early childhood. The average mercury content of each type of fish was calculated based on FDA data and information from other sources. The updated advice cautions parents of young children and certain women to avoid seven types of fish that typically have higher mercury levels: tilefish from the Gulf of Mexico; shark; swordfish; orange roughy; bigeye tuna; marlin; and king mackerel.

For fish caught recreationally, consumers are urged to check for local advisories where they are fishing and gauge their fish consumption based on any local and state advisories for those waters. If no information on fishing advisories is available, eat just one fish meal a week from local waters and also, avoid other fish that week. Consumers should clean and trim the fish they catch of fat and skin, since locally-caught fish may contain contaminants besides mercury that can be reduced by proper trimming and cooking, (e.g. broiling instead of frying can reduce some contaminants by letting fat drip away from the fish).

"It's all about eating and enjoying fish of the right kind and in the right amounts," said EPA Director for Water Science and Technology, Elizabeth Southerland, Ph.D. "This joint advice not only provides information for fish consumers who buy from local markets, but it also contains good information for people who catch their own fish or are provided fish caught by friends or relatives."

All retailers, grocers and others are urged to post this new advice, including the reference chart listing fish to choose, prominently in their stores so consumers can make informed decisions when and where they purchase fish. The agencies will be implementing a consumer education campaign working with a wide array of public and private partners featuring the new advice.

In June 2014, the agencies issued draft advice which encouraged pregnant women and others to eat between 8 and 12 ounces of fish a week of fish "lower in mercury" but did not provide a list showing consumers which fish are lower in mercury. The advice issued today also takes into account more than 220 comments received from academia, industry, nongovernmental organizations and consumers as well as an external peer review of the information and method used to categorize the fish.

For More Information:

- Eating Fish: What Pregnant Women and Parents Should Know:http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm393070.htm

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

The EPA, a federal agency, works to protect all Americans from significant risks to human health and the environment where they live, learn and work. The agency focuses on all parts of society, from individuals to businesses and local governments. It develops regulations concerning natural resources, energy, transportation, agriculture, and industry and supports the various facets of environmental research and protection.

R017

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Jones, William
Sent: Thur 8/27/2015 5:47:48 PM
Subject: RE: Summary of call with HHS & USDA on fish advice

Cool – thanks!

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, August 27, 2015 12:42 PM
To: Smegal, Deborah; Natanblut, Sharon; Jones, William; Wathen, John
Subject: Summary of call with HHS & USDA on fish advice

If it's useful, here are my notes from the call yesterday. I captured a few things for us to keep in mind as we go along.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Barash, Shari
Sent: Tue 1/17/2017 9:51:04 PM
Subject: Re: Advice Call info for Betsy for 1/18

Oh well, Cara asked me to just have her do it!

Sent from my iPhone

On Jan 17, 2017, at 4:46 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

> Sara just asked me to send to her for Evelyn to print out and run down to Betsy before she leaves.
>
> **From:** Barash, Shari
> **Sent:** Tuesday, January 17, 2017 4:38 PM
> **To:** Larimer, Lisa <Larimer.Lisa@epa.gov>
> **Cc:** Wathen, John <Wathen.John@epa.gov>
> **Subject:** Re: Advice Call info for Betsy for 1/18
>
> Lisa,
>
> I will send to Betsy and cc you both. I think I want to do it from a computer so she doesn't end up with the older attachment.
>
> Shari
>
> Sent from my iPhone
>
> On Jan 17, 2017, at 3:45 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:
>
> > I found it a little disjointed, so I cleaned up the attachment a little. Also fixed some typos in the email:
> >
> > Betsy-

The webpages go live at 8:45 AM on Wed. 1/18/17. The press release is posted at 9:15 AM.

We have two calls for you to make at 9:15 AM:

Ex. 5 - Deliberative Process

Attachment shows which entities EPA is contacting (p. 1), suggested talking points (p. 2), and list of entities FDA is contacting (p. 3).

Shari, Sara, Lisa, and John

From: Wathen, John
Sent: Tuesday, January 17, 2017 3:07 PM
To: Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Advice Call info for Betsy for 1/18

Betsy-

The webpages go live at 8:45 AM 1/18/17. The press release is post 9:15 AM

They (FDA) have two calls for you to make:

Ex. 5 - Deliberative Process

Suggest talking points are included in the attached, as well as the list of entities FDA is calling.

Shari, Sara, Lisa, and John

John Wathen

Senior Science Advisor, Fish and Beach Programs

National Branch (4305 T)

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Standards and Health Protection Division

Office of Science and Technology

Office of Water

US Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, DC 20460

202-566-0367 phone

202-566-0409 fax

http://www.epa.gov/waterscience

<Fish advice rollout info & TPs 1-17-17.docx>

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]
From: Natanblut, Sharon
Sent: Tue 1/17/2017 9:32:30 PM
Subject: RE: chart graphic on web page

Lisa, are you guys all set for tomorrow? Let's stay in close touch in the morning via email, okay? Hopefully the FR notice will post around 8:45, FDA and EPA will post around 9:15, Betsy will make her calls, we'll make our calls, and we'll see what the media coverage is, what the stakeholder reaction is, and what we need to do next!

And then – and this is most important – we plan a celebration for the four of us at a great seafood restaurant!!!

Sharon

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, January 17, 2017 4:23 PM
To: Abi-Khattar, Cathy; Natanblut, Sharon
Cc: Smegal, Deborah; CFSAN-Webmaster
Subject: RE: chart graphic on web page

Thank you! If anything does change, please loop in my webmaster at Kearney.renee@epa.gov

From: Abi-Khattar, Cathy [mailto:Cathy.Abi-Khattar@fda.hhs.gov]
Sent: Tuesday, January 17, 2017 4:14 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>
Subject: RE: chart graphic on web page

Here is the current version of everything. Below are the links that each piece will have when we are live tomorrow. Hope that helps.

Please note, if any of the attached change again this evening, I will resend the new versions to you.

Thanks

Cathy

QA English page
http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm534873.htm

QA English PDF
http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM537120.pdf

QA Spanish page
http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm537141.htm

QA Spanish PDF
http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM537166.pdf

FDA and EPA's Response to External Peer Review on the FDA-EPA's Technical Information on the Development
http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessm

External Peer Review Report: FDA-EPA's Technical Information on Development of Fish Consumption Advice (this is the report done by contractors)
http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessm

Cathy Abi-Khattar

CFSAN Web Team

5001 Campus Dr

College Park, MD 20740

240-402-1906

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, January 17, 2017 3:21 PM
To: Natanblut, Sharon; Abi-Khattar, Cathy
Cc: Smegal, Deborah
Subject: RE: chart graphic on web page

I suppose we can link to yours, but I'll need the direct link for each document.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, January 17, 2017 3:08 PM
To: Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: chart graphic on web page

That was my understanding but we need Lisa to confirm.

From: Abi-Khattar, Cathy
Sent: Tuesday, January 17, 2017 3:08 PM
To: Larimer, Lisa; Natanblut, Sharon
Cc: Smegal, Deborah
Subject: Re: chart graphic on web page

The images I sent is what I have.

For the other pieces, I was under the impression EPA is linking to our pieces. Sharon can you confirm? I can send the pieces if EPA is posting separate copies.

Thanks!

Cathy Abi-Khattar
CFSAN Web Branch

From: Larimer, Lisa

Sent: Tuesday, January 17, 2017 3:03 PM

To: Abi-Khattar, Cathy; Natanblut, Sharon

Cc: Smegal, Deborah

Subject: RE: chart graphic on web page

Thanks. I tried exporting a jpg of the full chart from the pdf, but it didn't come out clearly. Do you have a better version?

In addition, my webmaster is asking for (508-compliant) pdfs of the following, which I don't have:

- Q&A in English
- Q&A in Spanish
- Summary of public comments and agency responses
- Peer review report

I'm hoping you have them?

From: Abi-Khattar, Cathy [mailto:Cathy.Abi-Khattar@fda.hhs.gov]
Sent: Tuesday, January 17, 2017 12:37 PM
To: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: chart graphic on web page

Here is the image of the fish advice PDF and the image we are using for social media.

Our website development works differently so not sure how their side is going to code the same look and feel that we went with. Attached is a screenshot of how our page will look.

Thanks

Cathy

Cathy Abi-Khattar

CFSAN Web Team

5001 Campus Dr

College Park, MD 20740

240-402-1906

From: Natanblut, Sharon
Sent: Tuesday, January 17, 2017 12:35 PM
To: Abi-Khattar, Cathy; Larimer, Lisa
Subject: RE: chart graphic on web page

Do you want to send both? I'm not sure either! Also, do they have what's going on our landing page?

From: Abi-Khattar, Cathy
Sent: Tuesday, January 17, 2017 12:34 PM
To: Natanblut, Sharon; Larimer, Lisa
Subject: RE: chart graphic on web page

I am not sure what exactly we need to send. The social media image or just an image of the PDF?

Cathy Abi-Khattar

CFSAN Web Team

5001 Campus Dr

College Park, MD 20740

240-402-1906

From: Natanblut, Sharon
Sent: Tuesday, January 17, 2017 12:31 PM
To: Larimer, Lisa; Abi-Khattar, Cathy
Subject: RE: chart graphic on web page

Cathy, did you get back to Lisa on this? I'd love if we gave them everything we have if that's possible. Thanks.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, January 17, 2017 10:15 AM
To: Natanblut, Sharon; Abi-Khattar, Cathy
Subject: chart graphic on web page

I think I mentioned that I really liked your idea of having the chart as a graphic on the web page. Since you've already converted it into graphic form, can I send that to my webmaster so she doesn't have to duplicate work that already been done?

Thanks!

Lisa

To: Wathen, John[Wathen.John@epa.gov]
From: Barash, Shari
Sent: Thur 11/12/2015 9:57:13 PM
Subject: RE: Call tomorrow

Thanks for understanding.

Shari Z. Barash

Acting Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Wathen, John
Sent: Thursday, November 12, 2015 4:54 PM
To: Barash, Shari <Barash.Shari@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Re: Call tomorrow

Fine- Lisa can certainly articulate all the salient points.

~John

From: Barash, Shari
Sent: Thursday, November 12, 2015 4:51 PM
To: Wathen, John; Hisel-Mccoy, Sara
Cc: Larimer, Lisa

Subject: RE: Call tomorrow

John,

I took off Betsy. As I understand it, Betsy wants it small and only she and Lisa will be there (Betsy will be the only one on the phone). Thanks for staying so tuned in on your vacation.

Shari

Shari Z. Barash

Acting Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Wathen, John
Sent: Thursday, November 12, 2015 4:49 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Martin, Jeanette <Martin.Jeanette@epa.gov>
Subject: Call tomorrow

Betsy-

Am I correct in assuming we will be receiving a call-in number for the call tomorrow?

~John

From: Southerland, Elizabeth
Sent: Thursday, November 12, 2015 3:41 PM
To: Hisel-Mccoy, Sara
Cc: Larimer, Lisa; Barash, Shari; Wathen, John
Subject: Re: Info for Joel on fish advice

Wonderful job! The only change I want is Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Once you make that change, send to Joel and copy me. Ask him to provide any comments or questions so we can revise this before the 1 PM meeting with ORD. I do not have access to a computer only iPhone so it is better if you send to him rather than me.

Sent from my iPhone

On Nov 12, 2015, at 3:21 PM, Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov> wrote:

> Betsy – I am reading now but I thought it would save time if I just forwarded directly. I don't have a sense of what would be too long for Joel. Do you? Sara
>
> **From:** Larimer, Lisa
> **Sent:** Thursday, November 12, 2015 3:15 PM
> **To:** Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>
> **Subject:** Info for Joel on fish advice
>
> Here you go! I hope it's not too long, but if this is our one shot, I didn't want to skimp too much.
>
> Pasting into the email, in case you're on Blackberry. May be tough to read that way, though:

Fish Advice – Additional Information

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

<Fish advice-info for Joel Beauvais.docx>

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Stuckey, Carla[Carla.Stuckey@fda.hhs.gov]; Thomas, Clayton (OS)[Clayton.Thomas@hhs.gov]; Tootle, William[William.Tootle@fda.hhs.gov]
From: Goitom, Mahlet
Sent: Fri 11/6/2015 4:10:48 PM
Subject: Senate Briefing on Seafood Advisory

Dear Colleagues,

The Senate Agriculture Appropriations Subcommittee reached out to FDA requesting a briefing to discuss the status of the pending Seafood Advisory for Pregnant Women. FDA leadership thought it would be helpful to have EPA attend the briefing. We plan to hold a pre-call to prepare for the briefing, and outline the topics that can and cannot be addressed. We would like to know if you all are available for an in-person briefing with the Committee on Monday, November 16th between 1 and 3pm or 4-430pm.

We look forward to hearing back.

Thank you,

Mahlet Goitom

Congressional Affairs Specialist / Office of Budget / FDA

8455 Colesville Road

Silver Spring, MD 20993-0002

Phone: 301-796-6832

BB: 301-512-7357

Email: Mahlet.Goitom@fda.hhs.gov

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Naidenko, Olga[Naidenko.Olga@epa.gov]
From: Natanblut, Sharon
Sent: Wed 7/1/2015 1:22:19 PM
Subject: Re: Don't hate me, but this might be another good Q&A for the fish advice

That would be awesome!

Sent from my BlackBerry 10 smartphone.

[redacted]

Hi,

Ex. 5 - Deliberative Process

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Jones, William
Sent: Monday, June 29, 2015 11:00 PM
To: Natanblut, Sharon; Larimer.Lisa@epa.gov; Smegal, Deborah; Bigler.Jeff@epa.gov; Wathen.John@epa.gov; Fontenelle.Samantha@epa.gov; Naidenko.Olga@epa.gov
Subject: Re: Don't hate me, but this might be another good Q&A for the fish advice

Good points, as usual, Sharon - quite a slippery slope - never as easy as it seems.

From: Natanblut, Sharon
Sent: Monday, June 29, 2015 05:19 PM
To: Jones, William; Larimer, Lisa <Larimer.Lisa@epa.gov>; Smegal, Deborah; Bigler, Jeff <Bigler.Jeff@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>; Naidenko, Olga <Naidenko.Olga@epa.gov>
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

I agree it's a good idea, but I would want to know how much time we're talking about. So,

Ex. 5 - Deliberative Process

From: Jones, William
Sent: Monday, June 29, 2015 5:01 PM

To: Larimer, Lisa; Natanblut, Sharon; Smegal, Deborah; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

I think that's a good catch! I'm tempted to try and wordsmith Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process haven't thought of something better yet.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Monday, June 29, 2015 4:53 PM
To: Natanblut, Sharon; Jones, William; Smegal, Deborah; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: Don't hate me, but this might be another good Q&A for the fish advice

Last week it occurred to me that we didn't have anything that addressed Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

I pulled it from the 2004 advice, with the tweaks shown:

Ex. 5 - Deliberative Process

Lisa Larimer, P.E.

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Jones, William[William.Jones@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Naidenko, Olga[Naidenko.Olga@epa.gov]
From: Smegal, Deborah
Sent: Wed 7/1/2015 1:10:58 PM
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Hi,

Ex. 5 - Deliberative Process

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Jones, William
Sent: Monday, June 29, 2015 11:00 PM
To: Natanblut, Sharon; Larimer.Lisa@epa.gov; Smegal, Deborah; Bigler.Jeff@epa.gov; Wathen.John@epa.gov; Fontenelle.Samantha@epa.gov; Naidenko.Olga@epa.gov
Subject: Re: Don't hate me, but this might be another good Q&A for the fish advice

Good points, as usual, Sharon - Ex. 5 - Deliberative Process

From: Natanblut, Sharon
Sent: Monday, June 29, 2015 05:19 PM
To: Jones, William; Larimer, Lisa <Larimer.Lisa@epa.gov>; Smegal, Deborah; Bigler, Jeff <Bigler.Jeff@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>; Naidenko, Olga <Naidenko.Olga@epa.gov>
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

I agree it's a good idea, but I would want to know how much time we're talking about. So,

Ex. 5 - Deliberative Process

From: Jones, William
Sent: Monday, June 29, 2015 5:01 PM
To: Larimer, Lisa; Natanblut, Sharon; Smegal, Deborah; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

I think that's a good catch! I'm tempted to try and wordsmith Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Monday, June 29, 2015 4:53 PM
To: Natanblut, Sharon; Jones, William; Smegal, Deborah; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: Don't hate me, but this might be another good Q&A for the fish advice

Last week it occurred to me that we didn't have anything that addressed Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E.

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Naidenko, Olga[Naidenko.Olga@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Jones, William
Sent: Thur 6/25/2015 2:49:26 PM
Subject: RE: 6th FDA-EPA meeting on fish advice

Works for me, although we will need to touch on it with you briefly when you arrive (at CFSAN ☺) as

Ex. 5 - Deliberative Process

From: Natanblut, Sharon
Sent: Thursday, June 25, 2015 10:35 AM
To: Larimer, Lisa; Jones, William; Smegal, Deborah; Wathen, John; Fontenelle, Samantha; Naidenko, Olga; Bigler, Jeff
Subject: RE: 6th FDA-EPA meeting on fish advice

I may not be able to arrive until 12:30 – so sorry but something urgent has arisen. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

-----Original Appointment-----
From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, June 11, 2015 4:26 PM
To: Larimer, Lisa; Natanblut, Sharon; Jones, William; Smegal, Deborah; Wathen, John; Fontenelle, Samantha; Naidenko, Olga; Bigler, Jeff
Subject: 6th FDA-EPA meeting on fish advice
When: Thursday, June 25, 2015 12:00 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: CFSAN CP Room 2E032

Conference line: 1-855-564-1700
Extension: Ex. 6 - Personal Privacy
Participant

To: Wathen, John[Wathen.John@epa.gov]
From: Fontenelle, Samantha
Sent: Mon 6/22/2015 8:18:32 PM
Subject: Automatic reply: Fish advice chart

I am currently away and will respond to your email when I return.

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Frey, Sharon[Frey.Sharon@epa.gov]; Barash, Shari[Barash.Shari@epa.gov]; Buffo, Corey[Buffo.Corey@epa.gov]; Keating, Jim[Keating.Jim@epa.gov]; Martinez, Menchu[martinez.menchu-c@epa.gov]; Vlcan, Manjali[Vlcan.Manjali@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Wilcut, Lars[Wilcut.Lars@epa.gov]
From: Fabiano, Claudia
Sent: Thur 8/27/2015 2:54:06 PM
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

Ex. 5 - Deliberative Process

From: Larimer, Lisa
Sent: Wednesday, August 26, 2015 3:06 PM
To: Frey, Sharon; Barash, Shari; Buffo, Corey; Fabiano, Claudia; Keating, Jim; Martinez, Menchu; Vlcan, Manjali; Wathen, John; Wilcut, Lars
Subject: RE: Please send Friday staff meeting items by 11:00 am tomorrow

EPA-FDA fish advice

Ex. 5 - Deliberative Process

From: Frey, Sharon
Sent: Wednesday, August 26, 2015 2:43 PM
To: Barash, Shari; Buffo, Corey; Fabiano, Claudia; Keating, Jim; Larimer, Lisa; Martinez, Menchu; Vlcan, Manjali; Wathen, John; Wilcut, Lars
Subject: Please send Friday staff meeting items by 11:00 am tomorrow

If I receive nothing, I'll assume you have nothing.

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]
From: Smegal, Deborah
Sent: Thur 8/20/2015 4:39:17 PM
Subject: revised Q and As and technical appendix
technical web page-fish advice-08.20.15 EPA edits.docx
Fish Advice Qs and As-8.20.15 EPA edits.docx

Hi,

There include the changes we discussed today.

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]
From: Natanblut, Sharon
Sent: Thur 8/20/2015 1:56:08 PM
Subject: FW: FDA Fish chart (vertical and horizontal)
FISH_CHART_H_8.19.pdf
FISH_CHART_V_8.19.pdf

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
Cc: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]
From: Smegal, Deborah
Sent: Wed 8/19/2015 8:26:15 PM
Subject: FW: latest versions of advice documents
FRDTS#2015-646-draft FR notice-fish consumption advice revised red-line version 7 28 15jw8-12-15.docx
technical web page-fish advice-072315 (RO 7-29-15) (2) dcs 8 6 15 (RO 8-5-15) PT dcs 8 12 15jw8-12-15.docx

Hi Lisa,

I got your email, I… I searched my in box and these are the only electronic comments I could find that you sent us last week. You emailed some comments that we incorporated, but they were only in an email.

Did I miss something?

Regards,

DEbbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Wednesday, August 12, 2015 2:10 PM
To: Smegal, Deborah; Natanblut, Sharon; Jones, William; Larimer, Lisa
Cc: Fontenelle, Samantha; Bigler, Jeff
Subject: RE: latest versions of advice documents

Forgot the docs.

~John

From: Wathen, John
Sent: Wednesday, August 12, 2015 2:07 PM
To: 'Smegal, Deborah'; Natanblut, Sharon; Jones, William; Larimer, Lisa
Cc: Fontenelle, Samantha; Bigler, Jeff
Subject: RE: latest versions of advice documents

I had only two places where I suggest V. minor changes. One is in the technical page **How FDA and EPA derived the categories in the fish chart.** An added that and clarification of the number of servings that were contemplated.

The second change suggested is on p 7 of the FRN where I think the passive voice of "used" is more appropriate.

~John

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Wednesday, August 12, 2015 11:27 AM
To: Natanblut, Sharon; Jones, William; Larimer, Lisa; Wathen, John
Subject: latest versions of advice documents

Hi,

Thanks for the great and productive call today. As we discussed, here are the latest versions of the documents with all the track changes, including the most recent language we agreed upon on today's call that was inserted in the technical appendix.

I do not have an updated fish chart but as indicated the only change was "Ex. 5 - Deliberative Process" rather than "Ex. 5 - Deliberative Process".

Please let me know if you have questions.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Jones, William[William.Jones@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Smegal, Deborah
Sent: Wed 8/19/2015 7:41:58 PM
Subject: clean versions of FR notice and summary of response to comments
FRDTS#2015-646-draft FR notice-fish consumption advice revised clean version 8.19.2015 (3) (2).docx
Summary Table of Response to Public comments 8.19.15 clean.docx
Response to comments (RO 7-31-15) (2) dcs 8.12.15 (RO 8-15-17)8.19.15.docx
FISH_CHART_H_8.19.pdf
FISH_CHART_V_8.19.pdf

Hi,

Attached are the latest FDA cleared versions of the FR notice and the summary of the response to comment document. In addition I am including the latest pdf versions of the chart for discussion on tomorrow's call.

Ex. 5 - Deliberative Process

Looking forward to our conference call tomorrow at 9:30 am.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Jones, William[William.Jones@fda.hhs.gov]
From: Smegal, Deborah
Sent: Wed 8/19/2015 6:44:02 PM
Subject: RE: HOLD: FDA-EPA meeting to consolidate edits
Fish Advice Qs and As-8.18.15_clean.docx
technical web page-fish advice-08.18.15 clean.docx
Fish Advice Qs and As-8.13.15 (RO 8-14-15).docx
technical web page-fish advice-072315 (RO 7-29-15) (2) dcs 8.6.15 (RO 8-5-15).PT_dcs 8.12.15 (RO 8-14-15) (RO 8-17-15)8.18.15.docx

Opps…forgot the attachments.

Here they are.

debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Smegal, Deborah
Sent: Wednesday, August 19, 2015 9:33 AM
To: Natanblut, Sharon; Wathen, John; Larimer, Lisa; Bigler, Jeff; Jones, William
Subject: RE: HOLD: FDA-EPA meeting to consolidate edits

Hi,

Here are 2 of the cleared documents (Q and As and technical appendix) that I cleaned up by accepting the track changes and removing the comment bubbles. I also re-read to fix spacing and punctuation.

Attached are both the clean version (dated 8.18.15) and also the OCC cleared version in track changes.

I will get the final NOA (FR notice) and comment summary table and send shortly.

Hope this assists.

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Natanblut, Sharon
Sent: Wednesday, August 19, 2015 9:27 AM
To: Wathen, John; Larimer, Lisa; Bigler, Jeff; Smegal, Deborah; Jones, William
Subject: RE: HOLD: FDA-EPA meeting to consolidate edits

Fine with me. Deb, do you have the latest versions of everything you can send around?

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Wednesday, August 19, 2015 8:55 AM
To: Larimer, Lisa; Bigler, Jeff; Smegal, Deborah; Natanblut, Sharon; Jones, William
Subject: RE: HOLD: FDA-EPA meeting to consolidate edits

Maybe an abbreviated telephone check-in?

~John

From: Larimer, Lisa
Sent: Tuesday, August 18, 2015 5:00 PM
To: Wathen, John; Bigler, Jeff; Deborah Smegal (Deborah.smegal@fda.hhs.gov); Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov); Bill Jones (William.jones@fda.hhs.gov)
Subject: RE: HOLD: FDA-EPA meeting to consolidate edits

Do we still need to have this meeting?

-----Original Appointment-----
From: Larimer, Lisa
Sent: Thursday, August 06, 2015 1:57 PM
To: Larimer, Lisa; Wathen, John; Bigler, Jeff; Deborah Smegal (Deborah.smegal@fda.hhs.gov); Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov); Bill Jones (William.jones@fda.hhs.gov)
Subject: HOLD: FDA-EPA meeting to consolidate edits
When: Thursday, August 20, 2015 9:30 AM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: TBD

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]
From: Natanblut, Sharon
Sent: Tue 8/18/2015 10:48:16 PM
Subject: RE: Reactions from EPA general counsel on fish advice

Ex. 5 - Deliberative Process

Thanks.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, August 18, 2015 5:08 PM
To: Wathen, John; Bigler, Jeff; Smegal, Deborah; Natanblut, Sharon; Jones, William
Subject: Reactions from EPA general counsel on fish advice

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Fri 9/18/2015 5:16:31 PM
Subject: Automatic reply: FDA-EPA Fish Advice briefing

I am out of the office until Monday, September 21. If you need a response in the interim, please contact Corey Buffo for issues related to nutrients or water quality standards at buffo.corey@epa.gov or 202-566-1279 or contact John Wathen for fish/beach issues at wathen.john@epa.gov or 202-566-0367.

Thanks,

Lisa

To: Wilcut, Lars[Wilcut.Lars@epa.gov]
Cc: McRae, Evelyn[McRae.Evelyn@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Barash, Shari
Sent: Fri 9/18/2015 4:12:30 PM
Subject: Re: OD Notes

Also add:
Citizen Science
- We held a super successful mini WQS Academy for about 55 3rd-5th graders at the Earth Conservation Corp on the Anacostia River with Forest Service and National Geographic. Thanks to Ibrahim Goodwin and Heather Goss for teaching and to Janita Agiurre for obtaining the materials.
(This is also a Betsy Shout Out item).

Fish Advice
- briefing for Stan M on 9/22
- materials provided to Octavia and Rita Schoney

WQS Reg Rev (in addition to item Lars provided)
-announcement for webinars went out on WQS list serve on 9/17 also to ACWA and Felcia Wright
-registration page is live

Sent from my iPhone

On Sep 18, 2015, at 11:07 AM, Wilcut, Lars <Wilcut.Lars@epa.gov> wrote:

- **WQS Final Rule**: The correction notice to delete the statement regarding judicial review was signed by Ken on 9/18.

From: McRae, Evelyn
Sent: Friday, September 18, 2015 10:56 AM
To: Barash, Shari; Wilcut, Lars; Wathen, John
Subject: FW: OD Notes

Reminder: please send national Branch items for OD weekly meeting.

Regards, Evelyn M.

202.566.1018

From: Buffo, Corey
Sent: Friday, September 18, 2015 9:56 AM
To: McRae, Evelyn
Subject: OD Notes

Regional Branch

Ex. 5 - Deliberative Process

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Bigler, Jeff[Bigler.Jeff@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Naidenko, Olga[Naidenko.Olga@epa.gov]; Jones, William[William.Jones@fda.hhs.gov]
From: Natanblut, Sharon
Sent: Thur 6/11/2015 3:21:20 PM
Subject: RE: Agreed upon changes to fish advice chart

Thanks!!!

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, June 11, 2015 11:17 AM
To: Natanblut, Sharon
Cc: Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga; Jones, William
Subject: Agreed upon changes to fish advice chart

Ex. 5 - Deliberative Process

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Naidenko, Olga[Naidenko.Olga@epa.gov]; Olga Naidenko[olga.naidenko@gmail.com]
From: Bigler, Jeff
Sent: Tue 5/19/2015 6:41:38 PM
Subject: Re: response to comments-fish advice

Tried calling but no answer.....

Sent from Jeff Bigler by IPhone

> On May 19, 2015, at 12:00 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:
>
> Jeff, just call the conference room at Ex. 6 - Personal Privacy
>
> <meeting.ics>

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Bigler, Jeff
Sent: Tue 5/19/2015 5:03:36 PM
Subject: Re: Today's meeting on fish advice

Ex. 5 - Deliberative Process

On May 19, 2015, at 12:18 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

It looks like everyone (including me) will be unavailable for part of the time I originally reserved, and Olga and Samantha are out. That's fine; just pop in when you can.

To make the best use of our time, let's do some prep by email. Take a look. If you have a chance, offer thoughts by email beforehand.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

<portion examples.pdf>

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Bigler, Jeff
Sent: Tue 5/19/2015 2:34:22 PM
Subject: Re: Follow-up from May 15 FDA-EPA fish advice meeting

You are welcome!
BTW - I have to sign off from our 2:30 pm meeting today at 3:30 pm for another appt.

On May 19, 2015, at 9:48 AM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

Thanks!

From: Bigler, Jeff
Sent: Monday, May 18, 2015 10:04 AM
To: Larimer, Lisa
Cc: Wathen, John
Subject: RE: Follow-up from May 15 FDA-EPA fish advice meeting

Here are the comments that were included from Healthy Mothers, Healthy Babies (#214) related to the fetus. There are other comments from them regarding language (e.g., servings instead of ounces)

Synthesized Comments table:

Page 4, "Provide more information on the benefits of eating fish while pregnant, such as the development it supports in the fetus, and more specifically what the dangers are in not getting enough of the fatty acids (D202, D0214, D0221, D0213, D0219, D0138, D0227, 0097, 0095,)" and "Stress that there is evidence showing moderate levels of fish consumption has a significant and positive effect on a fetus/child's IQ (D0206, D0214, D0219)"

Page 7, "Stress that there is evidence showing moderate levels of fish consumption has a significant and positive effect on a fetus/child's IQ (D0206, D0214, D0219)"

In the All Public Comments doc:

Page 18, "The new advice retains the recommendation that expecting moms should "limit white (albacore) tuna to 6 ounces a week." However, according to data in your net effects report which evaluates the benefits of seafood at the species level [A Quantitative Assessment of the Net Effects on Fetal Neurodevelopment From Eating Commercial Fish (As Measured by IQ and also by Early Age Verbal Development in Children, available at: http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm393211.htm], pregnant women can safely consume up to 67 ounces of canned albacore tuna per week - that's 33 servings per week and more than 11 times the limit you are proposing to recommend. This recommendation is not scientifically justified. (FDA-2014-N-0595-0047/FDA-2014-N-0595-0049, similar comments in FDA-2014-N-0595-0097, FDA-2014-N-0595-DRAFT-0206, FDA-2014-N-0595-DRAFT-0214, FDA-2014-N-0595-DRAFT-0217, FDA-2014-N-0595-DRAFT-0218, FDA-2014-N-0595-DRAFT-0221, FDA-2014-N-0595-DRAFT-0227, FDA-2014-N-0595-DRAFT-0232) "

Page 25, "The advisory might be more effective if there is more information on the benefits of eating fish while pregnant, such as the development it supports in the fetus, and more specifically what the dangers are in not getting enough of the fatty acids (FDA-2014-N-0595-DRAFT-0110). Benefits to highlight include cardiovascular health for mothers and neurodevelopmental and eye benefits to children (FDA-2014-N-0595-DRAFT-0202, FDA-2014-N-0595-DRAFT-0214, FDA-2014-N-0595-DRAFT-0221). It is important to explain to women why seafood intake in the childbearing years is the best advice we can give for their current and future health, and the development of their infants. This advice will empower women to choose seafood intake on a regular basis. (FDA-2014-N-0595-DRAFT-0213, FDA-2014-N-0595-DRAFT-0219)"

Page 42, "The message to the public should stress that there is evidence showing moderate levels of fish consumption has a significant and positive effect on a fetus/child's IQ. More women would heed this advice and attain benefits for themselves and their children if the overall message was more positive and encouraging- shift to positive framing. (FDA-2014-N-0595-DRAFT-0206, FDA-2014-N-0595-DRAFT-0214, FDA-2014-N-0595-DRAFT-0219)"

From: Larimer, Lisa
Sent: Thursday, May 14, 2015 1:33 PM
To: Bigler, Jeff
Cc: Wathen, John
Subject: Follow-up from May 15 FDA-EPA fish advice meeting

Hi Jeff,

Sorry you missed the meeting this week. It was a productive one. Sharon mentioned there were some late comments and wanted to make sure our comment response table captured those. I thought they did, but wanted to make sure. In particular, she wanted to know if the one from Healthy Mothers, Healthy Babies that discussed fetus vs. unborn child made it in. Can you please check on that?

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Barash, Shari[Barash.Shari@epa.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Keating, Jim[Keating.Jim@epa.gov]; Fabiano, Claudia[Fabiano.Claudia@epa.gov]
From: Buffo, Corey
Sent: Mon 7/27/2015 12:50:02 PM
Subject: RE: Lisa out today - sick kids

Yikes, sorry to hear that.

I wouldn't give him anything for "review" unless Betsy thinks she needs to. My guess is if there is one it would be the federal register notice. But I imagine you will have to share the chart with him regardless, as this is all about the chart.

From: Larimer, Lisa
Sent: Monday, July 27, 2015 8:39 AM
To: Buffo, Corey; Barash, Shari; Wathen, John
Cc: Keating, Jim; Fabiano, Claudia
Subject: Lisa out today - sick kids

One has strep, the other a full blown cold & hopefully not a sinus infection. I don't have anything that can't wait until tomorrow. I've got a presentation ready for Ken on Thursday.

Ex. 5 - Deliberative Process

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Jones, William
Sent: Wed 8/12/2015 3:57:23 PM
Subject: RE: latest versions of advice documents

Now I see that Debbie had included this as well – sorry for the confusion. The version I subsequently sent had one very minor change at the very end to the two new sentences that

Ex. 5 - Deliberative Process

From: Jones, William
Sent: Wednesday, August 12, 2015 11:36 AM
To: Smegal, Deborah; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Subject: RE: latest versions of advice documents

And here's the NOA FR notice.

From: Smegal, Deborah
Sent: Wednesday, August 12, 2015 11:27 AM
To: Natanblut, Sharon; Jones, William; Larimer, Lisa; Wathen, John
Subject: latest versions of advice documents

Hi,

Thanks for the great and productive call today. As we discussed, here are the latest versions of the documents with all the track changes, including the most recent language we agreed upon on today's call that was inserted in the technical appendix.

I do not have an updated fish chart but as indicated the only change was "Ex. 5 - Deliberative Process" rather than "Ex. 5 - Deliberative Process".

Please let me know if you have questions.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Jones, William
Sent: Wed 8/12/2015 2:24:36 PM
Subject: RE: Discuss requested edits to fish advice

Ex. 5 - Deliberative Process

-----Original Appointment-----
From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, August 06, 2015 1:59 PM
To: Larimer, Lisa; Wathen, John; Bigler, Jeff; Smegal, Deborah; Natanblut, Sharon; Jones, William
Subject: Discuss requested edits to fish advice
When: Wednesday, August 12, 2015 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: by phone

855-564-1700
Conference code
Participant code Ex. 6 - Personal Privacy

To: Wathen, John[Wathen.John@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Jones, William
Sent: Wed 9/30/2015 7:23:25 PM
Subject: RE: sign-offs on fish advice

Ex. 5 - Deliberative Process

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Wednesday, September 30, 2015 2:43 PM
To: Jones, William; Larimer, Lisa
Cc: Smegal, Deborah; Natanblut, Sharon
Subject: RE: sign-offs on fish advice

Lisa and I could come out to CP Mon PM, **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

~John

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Wednesday, September 30, 2015 2:11 PM
To: Larimer, Lisa
Cc: Smegal, Deborah; Wathen, John; Natanblut, Sharon
Subject: RE: sign-offs on fish advice

Working on this.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, September 30, 2015 1:14 PM
To: Smegal, Deborah; Jones, William; Wathen, John; Natanblut, Sharon
Subject: sign-offs on fish advice

Can I get a list of who within HHS (including FDA I assume) has cleared the advice so far and what level/position they are? Would really like to have this before 10:30 tomorrow.

-Lisa

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
Cc: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Jones, William
Sent: Tue 8/11/2015 3:24:51 PM
Subject: RE: Discuss requested edits to fish advice

This edited section from the technical appendix is one of the things we want to discuss:

Ex. 5 - Deliberative Process

-----Original Appointment-----
From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, August 06, 2015 1:59 PM
To: Larimer, Lisa; Wathen, John; Bigler, Jeff; Smegal, Deborah; Natanblut, Sharon; Jones, William
Subject: Discuss requested edits to fish advice
When: Wednesday, August 12, 2015 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: by phone

855-564-1700
Conference code
Participant code Ex. 6 - Personal Privacy

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Jones, William
Sent: Wed 9/30/2015 6:11:05 PM
Subject: RE: sign-offs on fish advice

Working on this.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, September 30, 2015 1:14 PM
To: Smegal, Deborah; Jones, William; Wathen, John; Natanblut, Sharon
Subject: sign-offs on fish advice

Can I get a list of who within HHS (including FDA I assume) has cleared the advice so far and what level/position they are? Would really like to have this before 10:30 tomorrow.

-Lisa

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Bigler, Jeff
Sent: Mon 7/20/2015 6:42:20 PM
Subject: Re: Contact in CHPO on EPA-FDA fish advisory progress

But Martha usually has the final say before the office director.

□ □ □ □ □

On Jul 20, 2015, at 2:41 PM, Bigler, Jeff <Bigler.Jeff@epa.gov> wrote:

Yes, I've worked with Ted for 25 years on the fish advice and other fish related topics. He's a good guy.

On Jul 20, 2015, at 2:32 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

FYI. Do you know him?

From: Berger, Martha
Sent: Monday, July 20, 2015 2:30 PM
To: Larimer, Lisa
Cc: Coopwood, Theodore
Subject: RE: Would like to update someone in CHPO on EPA-FDA fish advisory progress

Hi Lisa,

Ted Coopwood will follow up with you on this, as he is our point person for fish advisory related work.

Thanks,

Martha

Martha Berger

Office of Children's Health Protection

US Environmental Protection Agency

202/564-2191

From: Larimer, Lisa
Sent: Friday, July 17, 2015 11:57 AM
To: Berger, Martha
Subject: Would like to update someone in CHPO on EPA-FDA fish advisory progress

Hi Martha,

This is a bit of a shot in the dark because I'm relatively new to the fish advice work and I'm not sure who, if anyone, our office has contacted in the past about this. The workgroup has reviewed comments from the public on the 2014 draft version of the fish advisory for pregnant women and children and has almost finalized everything. We received comments from the Children's Health Protection Advisory Committee, and I found your name associated with that committee. We are not looking to meet with CHPAC itself but would like to meet with someone, probably at the staff level, in the Children's Health Protection Office to let them know what the final version of the advice is likely to look like and how we addressed CHPAC's comments.

If you could let me know if you are the correct person, or if not then who is, and I'd be happy to set up a meeting with my team. We'd like to do it before we brief our AA on July 30.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Jones, William
Sent: Wed 8/5/2015 5:58:30 PM
Subject: RE: Let me know when's a good time to call you

Yes…I hope we get the go ahead sooner rather than later.

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Wednesday, August 05, 2015 1:56 PM
To: Jones, William; Larimer, Lisa
Cc: Natanblut, Sharon; Smegal, Deborah
Subject: RE: Let me know when's a good time to call you

One thing I would mention, Bill, is that Holly indicated she was working from the draft advice and not our latest and best.

~John

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Wednesday, August 05, 2015 1:53 PM
To: Larimer, Lisa
Cc: Wathen, John; Natanblut, Sharon; Smegal, Deborah
Subject: RE: Let me know when's a good time to call you

Our Center Director has contacted our Chief Counsel directly to see if we can do this yet…waiting to hear back. I was just drafting a response Holly letting her know this in so many word, while looping you in so you would see our response. I will send that now, then will forward to Debbie, Sharon and John so we're all on the same page.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, August 05, 2015 1:40 PM
To: Jones, William; Smegal, Deborah
Cc: Wathen, John; Natanblut, Sharon
Subject: FW: Let me know when's a good time to call you

In case Sharon is indisposed.... Ideally we'd like to call HHS back tomorrow morning.

From: Larimer, Lisa
Sent: Wednesday, August 05, 2015 12:54 PM
To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)
Subject: Let me know when's a good time to call you

John and I left you a VM. Bottom line is our mgmt got a call from Holly McPhee in HHS about our joint fish advice and the dietary guidelines. We wanted to talk to you before we called her back.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Jones, William
Sent: Wed 8/5/2015 5:52:47 PM
Subject: RE: Let me know when's a good time to call you

Our Center Director has contacted our Chief Counsel directly to see if we can do this yet…waiting to hear back. I was just drafting a response Holly letting her know this in so many word, while looping you in so you would see our response. I will send that now, then will forward to Debbie, Sharon and John so we're all on the same page.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, August 05, 2015 1:40 PM
To: Jones, William; Smegal, Deborah
Cc: Wathen, John; Natanblut, Sharon
Subject: FW: Let me know when's a good time to call you

In case Sharon is indisposed…. Ideally we'd like to call HHS back tomorrow morning.

From: Larimer, Lisa
Sent: Wednesday, August 05, 2015 12:54 PM
To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)
Subject: Let me know when's a good time to call you

John and I left you a VM. Bottom line is our mgmt got a call from Holly McPhee in HHS about our joint fish advice and the dietary guidelines. We wanted to talk to you before we called her back.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Hisel-Mccoy, Sara[Hisel-McCoy.Sara@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Southerland, Elizabeth
Sent: Tue 9/29/2015 8:17:53 PM
Subject: Re: HHS briefing just rescheduled for Friday!

Ex. 5 - Deliberative Process

Sent from my iPhone

On Sep 29, 2015, at 1:35 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

Ex. 5 - Deliberative Process

From: Southerland, Elizabeth
Sent: Tuesday, September 29, 2015 2:31 PM
To: Larimer, Lisa
Cc: Hisel-Mccoy, Sara; Wathen, John
Subject: Re: HHS briefing just rescheduled for Friday!

Ex. 5 - Deliberative Process

Sent from my iPhone

On Sep 29, 2015, at 11:18 AM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

Just to keep you all in the loop, I just got off the phone with Debbie Smegal from FDA, on our fish advice workgroup.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Southerland, Elizabeth
Sent: Tuesday, September 29, 2015 11:57 AM

To: Hisel-Mccoy, Sara; Wathen, John; Larimer, Lisa
Subject: Fwd: HHS briefing just rescheduled for Friday!

Thank God we have more time

Sent from my iPhone

Begin forwarded message:

> **From:** "Natanblut, Sharon" <Sharon.Natanblut@fda.hhs.gov>
> **Date:** September 29, 2015 at 10:30:44 AM CDT
> **To:** "Betsy Southerland (southerland.elizabeth@epa.gov)" <southerland.elizabeth@epa.gov>, "Larimer, Lisa" <Larimer.Lisa@epa.gov>
> **Cc:** "Jones, William" <William.Jones@fda.hhs.gov>, "Smegal, Deborah" <Deborah.Smegal@fda.hhs.gov>
> **Subject: HHS briefing just rescheduled for Friday!**

To: Wathen, John[Wathen.John@epa.gov]
Cc: jwath[Ex. 6 - Personal Privacy]
From: John Wathen
Sent: Sat 1/14/2017 2:52:10 PM
Subject: FDA Calls 1-14
FDA Rollout calls 1-14-17.docx

Yep today

To: Wathen, John[Wathen.John@epa.gov]
From: Smegal, Deborah
Sent: Tue 4/14/2015 12:12:03 PM
Subject: Re: Second FDA-EPA Meeting on Fish Advice

Thanks

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Tuesday, April 14, 2015 07:57 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Robiou, Grace <Robiou.Grace@epa.gov>; Bigler, Jeff <Bigler.Jeff@epa.gov>; Naidenko, Olga <Naidenko.Olga@epa.gov>; Carrington, Clark D; Natanblut, Sharon; 'William.jones@fda.hhs.gov' <'William.jones@fda.hhs.gov'>; 'Deborah.smegal@fda.hhs.gov' <'Deborah.smegal@fda.hhs.gov'>; Elkin, Ted
Subject: RE: Second FDA-EPA Meeting on Fish Advice

FDA colleagues-

Let's see who's on their smart phones this AM. Given the pretty steady rain, it may benefit overall dryness for you to come in through the indoor route. When you come up the Federal Triangle escalator, turn left and you are facing the entrance of William J Clinton South (WJCS).

You can enter the complex there, sign in there, and I can come meet you there (202-566-0367). For anyone driving, you can still come to the Constitution Ave entrance, but if I am picking folks up at WJCS, I won't be at my desk, so here is my cell- Ex. 6 - Personal Privacy

I look forward to our meeting today.

~John

From: Larimer, Lisa
Sent: Monday, April 13, 2015 1:05 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: RE: Second FDA-EPA Meeting on Fish Advice

Hi everyone. Here is the agenda and handouts 1, 2, 5 and 6 for tomorrow's meeting.
[Sharon, if you bring or send the electronic file with the projected mark-ups to the advice, I can project it on the big screen.]

Logistics:
Enter through the EPA West entrance at 1301 Constitution Ave, NW (same one as before) – Federal Triangle metro stop.
Call John Wathen at 202-566-0367 to lead you up.
Meeting will be in 6105A.
Call-in number is 855-564-1700; conference extension = **Ex. 6 - Personal Privacy**

We look forward to seeing you! We have a jam-packed agenda.

<< File: Agenda-Fish Advice-041415 FDA-EPA mtg.docx >> << File: Handout 1 Summary of All Public Comments on Advice-040715.docx >> << File: Handout 2 Fish advice chart-041315.xlsx >> << File: Handout 5 Annotated QA-040715.docx >> << File: Handout 6 Table of Synthesized Comments-040715.docx >>

Lisa Larimer, P.E.
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☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

-----Original Appointment-----
From: Robiou, Grace
Sent: Tuesday, March 17, 2015 3:31 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Larimer, Lisa; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: Second FDA-EPA Meeting on Fish Advice
When: Tuesday, April 14, 2015 9:00 AM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest6105AAssateague/DC-EPA-West-OST

To: Wathen, John[Wathen.John@epa.gov]
From: Ned Groth
Sent: Fri 1/13/2017 5:04:23 PM
Subject: Re: Phone number
Groth 2017, Scientific Foundations.pdf

Hello, John. Ex. 6 - Personal Privacy cell phone, only one I have)

Good to know you are still at EPA (unless alumni can still use the .gov email!) I have heard that a lot of good people have been retiring (Rita Schoeny, Jeff Bigler?) and I was worried about loss of institutional memory, even before the election.

How is morale holding up? I have faith in the tenacity of bureaucracies to keep doing what the law requires, even as each cohort of new politicos tries to interfere. Hope that spirit is embedded at EPA.

I don't know if you're on my email list so you may not have gotten my latest paper, attached. Enjoy.

Do you have any intelligence as to the status of the FDA/EPA Fish Consumption Advisory? My hope was that the "final" version would be much improved, based on the extensive critical comments received on the June 2014 draft, and I understand that FDA has been working on revisions, but the process has been almost completely opaque. I have no idea how much role EPA played in revisions, what the thrust of any changes might have been, or how close the final version may be to getting released, though it now looks as if it won't be out before January 20, which may mean all that work will go to waste. Any data you could share would be very welcome. I can keep it confidential if that's a condition.

Take care, and happy new year.

Ned Groth
nedgroth@cs.com

-----Original Message-----
From: Wathen, John <Wathen.John@epa.gov>
To: nedgroth <nedgroth@cs.com>
Sent: Fri, Jan 13, 2017 10:25 am
Subject: Phone number

Ned-

Would you please be so kind as to provide me with a current phone number to have on file for you?

Thanks,

~John Wathen

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Scientific foundations of fish-consumption advice for pregnant women: Epidemiological evidence, benefit-risk modeling, and an integrated approach

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a r t i c l e i n f o

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a b s t r a c t

Background: Pregnant women need fish consumption advice that increases seafood intake and simultaneously reduces methylmercury (MeHg) exposure. Two disciplines, epidemiology and benefit-risk modeling, can support such advice. Some current models suggest that fish consumption during pregnancy has only net beneficial effects. In contrast, many recent epidemiological studies have associated adverse effects on cognitive development with ordinary fish intake and MeHg doses routinely encountered by up to one in six US women of childbearing age. Proposed federal fish-consumption advice is based solely on a benefit-risk model. A more complete assessment integrating both types of evidence is needed.

Objectives and methods: The goal of this paper is to use a model to rank seafood items by their relative benefits and risks, producing consumer seafood choice recommendations that are also consistent with epidemiological observations. Recent epidemiological studies and benefit-risk models are reviewed, and model results are compared with one another and with epidemiological observations to identify commonalities that support inter-calibration.

Results and conclusions: Both approaches quantify MeHg doses at which harm slightly exceeds benefit. A model from the US Food and Drug Administration (FDA) predicts adverse effects at fish intakes containing, on average, more than 16 times the the US Reference Dose (RfD) for MeHg. Epidemiological results indicate that the RfD itself approximates a minimal adverse dose. This conceptual similarity allows FDA's model to be calibrated with the epidemiological results to generate fish intake recommendations that both the model and the epidemiology suggest should have substantially positive public health impacts.

1. Introduction

Fish consumption by women of childbearing age, especially during pregnancy, is a matter of substantial public health concern. (In this paper the terms “fish” and “seafood” are used interchangeably to encompass marine and freshwater finfish and shellfish.) Seafood is the principal dietary source of the omega-3 (n-3) polyunsaturated fatty acids (PUFAs), primarily Docosahexaenoic Acid (DHA) and Eicosapentaenoic Acid (EPA), essential for prenatal nervous system development (Hibbeln et al., 2007). But fish is also a source of methylmercury (MeHg), formed in the environment from inorganic mercury (Hg) emitted by natural and anthropogenic sources, and accumulated in aquatic food webs. MeHg is neurotoxic, and even mildly elevated exposure during gestation can damage the developing brain (Karagas et al., 2012).

Fish consumption during pregnancy thus poses significant benefit-risk tradeoffs for prenatal brain development. While nutritional guidelines urge 2–3 seafood meals (about 8-12 ounces) per week (DGA, 2015), the average American woman of childbearing age currently eats less than half that amount (FDA, 2014a). Concerns about MeHg appear to be one factor discouraging greater consumption (Lando and Lo, 2014).

An analysis of data from the National Health and Nutrition Examination Survey (NHANES) from 1999 through 2010 found that seafood intake among women of childbearing age remained stable, while blood Hg levels decreased moderately (Birch et al., 2014), which suggests that recent fish consumption advice has helped American women reduce MeHg exposure. On the other hand, the possible methylmercury exposure consequences of efforts to increase seafood consumption need careful assessment.

While advice simply to eat more seafood is important, which types of seafood women choose to eat also can affect health outcomes (Mahaffey et al., 2011). As Table 1 illustrates, popular fish

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0013-9351/

Table 1
Omega-3 and mercury content of selected popular fish and shellfish varieties.[a]

Seafood Item	n-3 s, mg/100 g	Hg, lg/100 g
Sardines	1190	2
Salmon	1180	2
Herring, Anchovies	2020	5
Shrimp	350	1
Pollock	530	4
Clams	200	2
Tilapia	90	1
Flounder, Sole	300	8
Tuna, Canned Albacore	860	35
Tuna, Canned Light	270	13
Cod	160	9
Lobster	200	11
Swordfish	900	100
Shark	690	98
Orange Roughy	30	57

[a] Source of data, US FDA (2014a, Table V-8).

and shellfish types vary widely in both n-3 and MeHg content. In practical terms, a woman who doubles her fish intake without changing her seafood selections will double her doses of both beneficial n-3 s and potentially harmful MeHg. But a woman who switches from eating, for example, 100 g/week each of cod and canned light tuna to 100 g/week each of salmon and shrimp would almost quadruple her n-3 intake, from 430 to 1530 mg. She would also reduce her MeHg dose from 22 to 3 mg, and substantially increase the benefit-risk ratio of her seafood meals. Fish consumption advice can thus improve health outcomes most effectively not only by persuading women to eat fish more often but also by guiding them to choose varieties with more n-3 s and less MeHg, and to avoid or limit consumption of varieties with the opposite profile.

Advice for pregnant women on how much seafood of which varieties to eat should rest on scientific understanding of the comparative benefits and risks of consuming different seafood choices. Two types of evidence can support such recommendations: epidemiological studies of benefits and risks of fish consumption during pregnancy, and benefit-risk models.

Each type of evidence has advantages, disadvantages and limitations. Epidemiology deals only with associations between environmental exposures (e.g., to n-3 s and MeHg) and outcomes, and repeated concordant findings from similar studies are generally required to establish and quantify any particular relationship. Studies of neurodevelopmental effects of fish consumption during pregnancy are subject to mutual negative confounding; i.e., beneficial and harmful effects tend to offset or obscure each other, making it more difficult to measure outcomes in either direction (Budtz-Jørgensen et al., 2007). Further, it is not feasible in an epidemiological study to record in detail what fish varieties women ate at various points during a pregnancy, or to associate positive or negative developmental outcomes with any particular seafood choices.

Models, on the other hand, incorporate some epidemiological data and use assumptions and data about seafood constituents and intakes to estimate the benefits, harm and net effects of different fish consumption choices. They can be powerful tools for comparing and contrasting relative benefits and risks of consuming different fish varieties in different scenarios. However, a model is only as good as the data and assumptions fed into it by the modelers, decisions that are quite subjective and often arbitrary. While policymakers may be tempted to overlook the uncertain nature of model results, practitioners of the discipline are certainly aware of its limitations. The statistician George Box, an early modeler, famously quipped, "All models are wrong, but some models are also useful" (see Box and Draper, 1987).

Ideally, epidemiological evidence and benefit-risk modeling would be used complementarily to provide the fullest and most balanced evidentiary basis for fish consumption advice, but that has not been the case. Simply stated, the different approaches have led to different conclusions, and advice based on the two disciplines has also varied markedly.

For example, two prominent recent models (FAO/WHO, 2011; FDA, 2014a) both suggest that eating any amount of any fish during pregnancy almost always has only net beneficial effects on neurodevelopment. Fish consumption advice for pregnant women recently proposed by four US agencies is based only on results of these models; the proposed advice stresses increasing fish intake and downplays the need to manage MeHg exposure (DGAC, 2015; FDA, 2014b).

In contrast, more than a dozen epidemiological studies published since 2005 (enumerated in the next section) indicate that for a substantial minority of children, adverse neurodevelopmental effects of prenatal MeHg exposure can outweigh beneficial nutritional effects of maternal fish consumption. The same evidence suggests that even for children with net benefits, the beneficial effect is significantly larger when MeHg exposure is minimized. Consequently, many research teams have urged pregnant women to eat more fish, but have also stressed the importance of choosing low-Hg varieties (e.g., Ginsberg and Toal, 2009; Karagas et al., 2012; Lederman et al., 2008; Oken et al., 2005, 2008a; Orenstein et al., 2014; Sagiv et al., 2012).

In short, results of population studies and prominent models have differed; epidemiological evidence contradicts the models, and advice based on the different approaches has diverged. To ground fish consumption advice more soundly on science, it is essential to resolve this conflict between modeling and epidemiology, to weigh both types of evidence in a balanced and integrated way.

2. Methods

A review of evidence from both disciplines was conducted to identify commonalities that support a synthesis. A crucial concept in both approaches is the "minimal adverse dose" (MAD) of methylmercury. In epidemiology, the MAD is the exposure level above which adverse effects are first observed. One model, the FDA's, predicts an intake for each seafood variety (and thus, the MeHg dose it contains) above which adverse effects just begin to outweigh beneficial effects, i.e., a model-derived MAD. By comparing results of both approaches quantitatively, the model can then be re-calibrated with MAD estimates from epidemiology.

FDA's model also identifies weekly intakes of each seafood variety above which net adverse effects first occur; these can be taken as maximum permissible intakes for each fish type. After recalibrating the model with an epidemiologically-derived MAD, new maximum weekly intakes were calculated for each seafood item. Those results were then arrayed in a seafood-choice chart for pregnant women, sorting varieties in terms of permissible weekly servings.

The step-by-step analysis leading to that end point is presented in the sections that follow. The epidemiological evidence is first reviewed and summarized. Four benefit-risk models are then reviewed and compared with each other and with the epidemiological data. The quantitative re-calibration of the FDA model by comparing its MADs with those from epidemiology is then carried out to produce the consumer choice chart. Finally, results of this analysis are discussed and compared with other seafood-choice advice based only on risk-benefit models.

3. Review of epidemiological evidence

The objective of this review is not to explore evidence in detail nor to assess the strengths and weaknesses of individual studies. Instead it provides an overview of quantitative estimates of beneficial effects of fish consumption during pregnancy, adverse effects of prenatal MeHg exposure, or net effects on cognitive development, for later comparison with estimates of those effects generated by benefit-risk models. Therefore, only studies that observed beneficial or adverse outcomes are included.

3.1. Early studies

Neurotoxic effects of MeHg in fish and the heightened vulnerability of the developing nervous system were first observed in the 1960s in severe industrial pollution incidents in Japan (Sakamoto et al., 2004; Yorifuji et al., 2013). Later research has explored whether MeHg exposure associated simply with seafood consumption, i.e., without localized pollution, may have similar if subtler adverse effects. Studies of populations with high-fish diets in New Zealand and the Faroe Islands (where the residents also eat high-Hg pilot whale meat) associated deficits in several cognitive developmental outcomes with prenatal MeHg exposure (Crump et al., 1998; Grandjean et al., 1997; Kjellstrom et al., 1986, 1989). A study in the Seychelles initially failed to associate any adverse effects with MeHg exposure (Davidson et al., 1998; Myers et al., 2003).

In exploring why their results differed, the Faroes and Seychelles research teams zeroed in on the possibility that beneficial effects on cognitive development from nutrients in fish and adverse effects of MeHg might have partially or fully obscured each other. Both groups developed improved statistical methods to adjust for this mutual negative confounding, and both subsequently reported that substantial confounding had in fact been present in their earlier data (Budtz-Jørgensen et al., 2007; Davidson et al., 2008; Strain et al., 2008).

3.2. Meta-analyses

A decade ago, two research teams did meta-analyses of data on cognitive developmental effects of MeHg (Axelrad et al., 2007; Cohen et al., 2005a); see results in Table 2. Cohen et al. (2005b) also developed a meta-analysis for cognitive benefits of maternal n-3 intake. No epidemiological data on the latter were then available, so Cohen et al. used data from clinical trials in which pregnant or lactating women were given n-3 supplements, which at best offer relatively weak, indirect evidence of possible benefits of eating fish.

Both meta-analyses of adverse cognitive developmental effects of prenatal MeHg exposure used the New Zealand data and early reports from the Faroes and Seychelles studies. Both of the latter data sets were subsequently shown to be seriously confounded by beneficial effects of fish consumption (Budtz-Jørgensen et al., 2007, Davidson et al., 2008; Strain et al., 2008); thus, both meta-analyses probably significantly underestimated the size of MeHg's adverse effects.

3.3. Recent studies: beneficial effects

Table 3 summarizes data on the neurodevelopmental benefits of maternal fish consumption during pregnancy. The number of studies is relatively small and all were published in the past decade or so.

The Avon Longitudinal Study of Parents and Children (ALSPAC), a large prospective cohort study in the United Kingdom, examined multiple factors that can affect neurodevelopment. Daniels et al. (2004) associated higher verbal development scores with maternal intake of 1–3 fish meals per week during pregnancy when compared with no fish consumption. The largest gains were associated with eating any fish meals per week compared to none, and no greater benefit was found with 4 or more seafood meals weekly, suggesting that beneficial effects reached a plateau at about 3 meals per week. Hibbeln et al. (2007) observed an odds ratio of 1.48 for low verbal IQ score in children whose mothers ate no fish or less than 12 ounces of fish per week, compared to children whose mothers ate more than 12 ounces weekly during pregnancy; improvements on other cognitive developmental outcomes were also associated with higher maternal fish consumption. Odds of having a low IQ decreased as maternal seafood intake increased across all three consumption levels, with no obvious plateau.

Oken et al., (2008b) analyzed data from the Danish National Birth Cohort and reported odds ratios of 1.25 at age 6 months and 1.29 at age 18 months of scoring higher on various developmental milestones for children of mothers in the highest quintile of fish intake during pregnancy, compared with the lowest quintile. This analysis also found continuous improvement in developmental status as fish consumption rose, i.e., no plateau of beneficial effects.

Gale et al. (2008), Lederman et al. (2008), Oken et al. (2005, 2008a), Sagiv et al. (2012) and Suzuki et al. (2010) have also reported beneficial effects of maternal fish consumption during pregnancy, in much smaller studies than the ALSPAC or Danish cohorts. These studies offer additional corroboration that maternal fish consumption during pregnancy has beneficial effects on cognitive development. No meta-analysis of data from these studies has yet been published.

3.4. Recent studies: MeHg effects

During the past decade the focus of research has shifted to whether MeHg exposure from eating ordinary amounts and types of fish might adversely affect cognitive development. Table 4 summarizes recent evidence on this topic.

The question, at what level of MeHg exposure are adverse effects (that is, either net adverse effects, or a substantial diminution of beneficial effects) likely to occur is obviously a key one for fish consumption advice. A reference point is therefore useful to define how much MeHg intake is deemed "acceptable," or conversely, "excessive." The US has established a Reference Dose (RfD) for MeHg for that purpose, and it is used here to help interpret results in Table 4. The RfD is described and explained in Sidebar A.

Studies summarized in Table 4 come from many countries and examine diverse cognitive outcomes in children ranging in age

Table 2
Meta-analyses of effects of omega-3 s and methylmercury on neurodevelopment: slopes for beneficial and adverse effects.

Authors/date	Slope, beneficial effect	Slope, adverse effect
Cohen et al. (2005a, 2005b)	þ 0.13 IQ point per 100 mg/day maternal intake of n-3 s	Central Estimate: ¬ 0.7 IQ point per 1 mg/g Hg in maternal hair Low estimate: ¬ 0.2 IQ point (Range: 0 to ¬ 1.5)
Axelrad et al. (2007)	not included in analysis	¬ 0.18 IQ point per 1 mg/g Hg in maternal hair (Range: ¬ 0.009 to ¬ 0.378)

Table 3
Recent studies of beneficial effects of maternal fish consumption during pregnancy.

Authors/Date	Country	N¼	Ages	Exposure Index, Break Point (s)	% w/ intake	Outcome Measure (s)	Results: Raw Scores	Results: Slope or β Coefficient [95% CI]	Results: Odds Ratio [95% CI]	Results: p value	Adjust for Hg?
Daniels et al. (2004)	UK	7,421	15 & 18 mo	fish meals/wk		1. MacArthur Communicative	Fish/Wk / MCDI/Vocab / DDST		Top 15% vs. bottom 15% fish intake		
				rare/none	12	Development Inventory @15 mo	0 / 68 / 7.1		OR for High Test Score		
				o 1 per wk	18	2. Denver Developmental	o 1 / 71 / 7.4		MCDI Vocabulary 1.5 [1.1, 2.0]	0.05	no
				1–3 per week	31	Screening Test @18 mo	1–3 / 73 / 7.4		MCDI Social 1.8 [1.4, 2.2]	0.02	no
				4 þ per week	39		4 þ / 72 / 7.4		DDST Language 1.3 [1.0, 1.8]	0.03	no
Oken et al. (2005)	US	135	6 mo	fish meals/wk		Visual Recognition Memory	mean 59.8, range 10.9–92.5	þ 4.0 VRM pts per fish meal			yes
				mean 1.2			low Hg, low fish, 60	[1.3, 6.7]			
				hi (4 2), n¼9	7		low Hg, high fish, 72				
				lo (o 2), n¼126	93		high Hg, low fish, 53				
							high Hg, high fish, 55				
Hibbeln et al. (2007)	UK	5,449	6, 18,	fish, g/wk		Primary Outcome: IQ at age 8			OR for Lowest Quartile Verbal IQ		
			30, 42,	none	12	measured with			no fish 1.48 [1.16,1.90]	0.0041	no
			81 mo,	1–340	65	Wechsler Intelligence Scale			1–340 g/wk 1.09 [0.92, 1.29]		
			8 yr	4 340	23	for Children, 3rd Ed. (WISC-III)			4 340 g/wk 1.0 (referent)		
(Oken et al., 2008a)	US	341	3 yr	fish meals/wk		1. Peabody Picture	Mean scores [7 SD]:	r 2 meals/wk, 4 2 vs.			
				mean 1.5 7 1.4		Vocabulary Test	PPVT, 105.7 7 13.8	2.2 [¹ 2.6, 7.0], PPVT			yes
				never, n ¼47	14		WRAVMA Drawing, 99.9 7 10.3	6.4 [2.1,10.7], WRAVMA Drawing			yes
				r 2/wk, n ¼201	74	2. Wide Range Assessment	WRAVMA Pegboard, 99.8 7 10.3	6.4 [2.0, 10.8] WRAVMA Total			yes
				4 2/wk, n ¼40	12	of Visual Motor Abilities	WRAVMA Matching, 107.8 7 14.1				
							WRAVMA Total, 103.2 7 10.5	no benefit, r 2 meals/wk vs. 0			
Oken et al. (2008b)	Denmark	25,446	6 mo	fish, g/wk		19 Developmental Milestones	Range of scores at 18 mo, 5–12	Change in OR for high score	OR for high developmental score,		
			18 mo	mean 186		at 18 mo and 13 DMs at 6 mo	85% of scores betw 6 and 9	at age 18 months	highest vs. lowest fish intake quintiles		
				none	3	scored by mothers on a		1.49 [1.33, 1.66]	1.29 [1.20, 1.38] at age 18 mo		no
				1–340	86	questionnaire via interview		per added fish meal/wk	1.25 [1.17,1.34] at age 6 mo		no
				4 340	11						
Gale et al. (2008)	UK	217	9 yr	fish meals/wk		1. Wechsler Abbreviated					
				never	9	Scale of Intelligence	þ 7.55 [0.75, 14.4] Verbal IQ		OR of "hyperactive" child, eating oily		
				r 1 per wk	25	2. Strengths & Difficulties	if mothers ate any fish during		fish in early pregnancy vs.		
				1 þ 2 per wk	47	Questionnaire (Goodman	late pregnancy, vs. no fi	sh	OR 0.34 [0.15, 0.78]		no
Lederman et al. (2008)	US	280	12, 24, 36, 48	types of fish 0, n ¼67	32	1. Bayley Scales of Infant Development, 2nd Ed.,	Ate fish vs. no fish: BSID Psychomotor Devel				

Table 3 (continued)

Authors/Date	Country	N¼	Ages	Exposure Index, Break Point (s)	% w/ intake	Outcome Measure (s)	Results: Raw Scores	Results: Slope or β Coefficient [95% CI]	Results: Odds Ratio [95% CI]	Results: p value	Results: Adjust for Hg?
			mo	1, n ¼46	22	at ages 1, 2 and 3 yr	Index @36 mo, þ 8.7			0.002	yes
				2, n ¼42	20	2. Wechsler Preschool and Primary	WPPSI Full IQ @48 mo, þ 5.64			o 0.001	yes
				Z 3, n ¼57	27	Scale of Intelligence at age 4 yr	WPPSI Verbal IQ @48 mo, þ 5.60			o 0.001	yes
Suzuki et al. (2010)	Japan	498	3 days	fish, g/wk		Neonatal Behavioral		Pearson Product-Moment			
				mean, 357		Assessment Scale:		Correlation Coefficient			
				S. D. 7 244		28 behavioral and 18 reflex		betw. fish intake and			
				median, 306		items scored in 7 clusters		Motor Cluster score, 0.102		0.03	yes
				range, 0.3–2,185		Focus on Motor Cluster					
Sagiv et al. (2012)	US	421	8 yr	fish meals/wk		Diagnosis of Attention Deficit			4 2 vs. r 2 fish meals/ week		
				mean, 3.7 7 3.9		Hyperactivity Disorder @ age 8,			OR of score above 86th percentile on		
				median, 2.3		Inattentive component &			Connors Rating Scale Components:		
				range, 0–7 22.6		Impulsive/Hyperactive component;			Inattentive, OR 0.6 [0.4, 0.9]		yes
				r 2, n ¼248	48	Based on computer lab evaluations,			Impuls/Hyperact, OR 0.4 [0.2, 0.6]		yes
				4 2, n ¼267	52	WISC-III Hyperactivity Scales, and Connors (teacher) ratings			Total ADHD, OR 0.6 [0.4, 0.9]		yes

Table 4
Recent studies of adverse effects of prenatal methylmercury exposure.

Authors/date	Country	N ¼	Ages	Exposure index, Break Points	% w/ exp	Outcome Measures	Results: Raw Scores	Results: Slope or β Coefficient [95% CI]	Results: Relative Risk/OR [95% CI]	Results: p value	Results: Adjust for ben?
Oken et al. (2005)	US	135	6 mo	Maternal hair Hg		Visual Recognition Memory	mean 59.8, range 10.9¬ 92.5	¬ 7.5 [¬ 13.7,¬ 1.2] per mg/g hair Hg			yes
				mean 0.55 mg/g			low Hg, low fish, VRM ¼60				
				min 0.02 mg/g			low Hg, high fish, VRM ¼72				
				max 2.38 mg/g			high Hg, low fish, VRM ¼53				
				low, o 1.2 mg/g	90		high Hg, high fish, VRM ¼55				
				high, Z 1.2 mg/g	10						
Jedrychowski et al. (2006)	Poland	233	1 yr	Maternal blood Hg		Bayley Scales of Infant Development, 2nd Ed. (BSID-II)	15% scored "Delayed" on BSID		RR for "delayed" score		
				GM 0.55 mg/L			MDI, 92.6 7 11.6 vs. 102.6 7 8.7		3.58 [1.40, 9.14] for cord blood		
				S. D. 7 0.06 mg/L		Two sub-indices:	PDI, 83.0 7 9.4 vs. 99.6 7 10.1		Hg 4 median, 0.80 mg/L		
				median 0.50 mg/L		Mental Development Index (MDI)	Hg, normal, 0.52 [0.46, 0.58] mg/L		2.82 [1.17,6.79] for maternal	0.0101	no
				min 0.10 mg/L		Psychomotor Devel. Index (PDI)	Hg, delayed, 0.75 [0.59, 0.94] mg/L		blood Hg 4 median, 0.50 mg/L		
				max 3.4 mg/L							
				low, r 1.0 mg/L	75						
				high, 4 1.0 mg/L	25						
Gao et al. (2007)	Zhoushan, China	384	3 days	Cord blood Hg		Neonatal Behavioral Neurological Assessments (NBNA)	Maximum NBNA score is 40		OR for decreased Behavior		
				GM 5.58 mg/L			94% of subjects scored Z 37		score if cord Hg 4 5.8 mg/L,	o 0.001	no
				high, 4 5.8 mg/L	70	Five clusters: Behavior, Passive	Behavior scores of boys were		1.235 [1.078, 1.414]		
				maternal hair Hg		Tone, Active Tone, Reflexes,	associated with Hg exposure				
				GM 1.25 mg/g		and General Assessment	(no other clusters, none in girls)				
Oken et al. (2008a)	US	341	3 yr	Maternal rbc Hg		1. Peabody Picture Vocabulary Test	Effect Estimates,	¬ 0.4 PPVT pts per ng/g Hg			yes
				mean 3.8 ng/g		2. Wide Range Assessment	Top decile Hg vs. lower 90%:	¬ 0.06 WRAVMA pts per ng/g Hg			yes
				S. D. 7 3.8 ng/g		of Visual Motor Abilities	PPVT,¬ 4.5 [¬ 8.5,¬ 0.4]				yes
				range 0.03¬ 21.9			WRAVMA,¬ 4.6 [¬ 8.3,¬ 0.9]				yes
				low, o 9.1 mg/g	90						
				high, Z 9.1 mg/g	10						
Lederman et al. (2008)	US	280	12, 24, 36, 48 mos	Cord blood Hg		1. Bayley Scales of Infant Development, 2nd Ed., at ages 1, 2 and 3 yr	Mean (7 S. D.) outcome scores:	β, Ln Cord Hg vs. outcome:			
				mean 7.82 mg/L			BSID MDI, 24 mo, 96.1 7 12.6	¬ 2.76		0.035	
				S. D. 9.71 mg/L			BSID PDI, 36 mo, 98.4 7 13.1	¬ 4.16		0.007	yes
				min 0.10 mg/L		2. Wechsler Preschool	Perf IQ, 48 mo,	¬ 3.45		0.023	

Table 4 (continued)

Authors/date	Country	N ¼	Ages	Exposure index, Break Points	% w/ exp	Outcome Measures	Results: Raw Scores	Slope or β Coefficient [95% CI]	Relative Risk/OR [95% CI]	p value	Adjust for ben?
						and Primary	100.7 7 13.9				
				max 63mg/L		Scale of Intelligence at age 4 yr	Verbal IQ, 48 mo, 95.7 7 13.2	┐ 2.92		0.023	
				GM 4.44mg/L			Total IQ, 48 mo, 97.6 7 12.7	┐ 3.76		0.002	
Suzuki et al. (2010)	Japan	498	3 days	Maternal hair Hg		Neonatal Behavioral Assessment		1. Pearson product-moment			
				mean 2.22mg/g		Scale, 28 behavioral items		correlation coefficient, hair Hg			
				S. D. 7 1.16mg/g		and 18 reflex items, 7 clusters		& motor cluster score: ┐ 0.126		0.01	yes
				median 1.96mg/g		Motor Cluster includes muscle		2. β coefficient, adjusted multiple			
				min 0.29mg/g		tone and movement		regression model: ┐ 0.116		o 0.05	yes
				max 9.35mg/g							
Sagiv et al. (2012)	US	421	8 yr	Maternal hair Hg		Diagnosis of Attention Deficit	Scores dichotomized at 86th		RR, Hair Hg Z 1mg/g vs. o 1mg/g		
				mean 0.62mg/g		Hyperactivity Disorder @ age 8,	percentile of Connors scale;		(fully adjusted model)		
				S. D. 7 0.57mg/g		Inattentive component &	RR's calculated of score above				
				median 0.45mg/g		Impulsive/Hyperactive component;	86th percentile (i.e., ADHD)		Inattentive, 1.3 [1.0, 1.7]		yes
				range 0.03┐ 5.14		Based on computer lab evaluations,			Impuls/Hyperact 1.6 [1.1,2.4]		yes
				high ¼ Z 1.0 mg/g	16	WISC-III Hyperactivity Scales,			Total ADHD Score 1.5 [1.1,2.0]		yes
				low ¼ o 1.0 mg/g	84	and Connors (teacher) ratings					
Lam et al. (2013)	Hong Kong, China	608	8 yr	Cord blood Hg		1. Hong Kong Version of Weschsler	1. Picture arrangement, HK-WISC				
				mean 10.0mg/L		Intelligence Scale for Children	low Hg 11.83, high Hg 11.53	β¼┐ 0.944 7 0.479		0.049	no
				S. D. 7 4.8mg/L		2. Hong Kong List Learning Test	2. Short-delay word re-call, HKLLT				
				median 9.2mg/L		3. Tests of Everyday Attention	low Hg ┐ 0.83, high Hg ┐ 1.40	β¼┐ 1.087 7 0.399		0.007	no
				max 36.9mg/L		for Children	3. Long-delay word re-call, HKLLT				
				low, r 5.8mg/L	19	4. Boston Naming test	low Hg ┐ 0.85, high Hg ┐ 1.36	β¼┐ 1.161 7 0.415		0.005	no
				high, 4 5.8mg/L	81	5. Grooved Pegboard Test					
Wu et al. (2014)	Zhoushan, China	418	3 days	Maternal blood Hg		Neonatal Behavioral Neurological	Hg exposure associations				
				mean 5.68mg/L		Assessments (NBNA)	with decreased score for:				
				S. D. 7 4.04mg/L		Five clusters: Behavior, Passive	Active muscle tone	β¼0.06 7 0.02	OR 1.06 [1.01,1.11]	0.017	no
				75%ile 8.19mg/L		Tone, Active Tone, Reflexes,	Passive muscle tone	β¼0.07 7 0.03	OR 1.07 [1.02,1.13]	0.0071	no
				low, r 5.8mg/L	44	and General Assessment	Primary reflexes	β¼0.09 7 0.05	OR 1.11[1.02,1.21]	0.0662	no

				high, 4 5.8mg/L	56		Total NBNA score	β¼0.03 7 0.01		0.0409	no
Orenstein et al. (2014)	US	393	7–11 yr	Maternal hair Hg		Wide Range Assessment		Each 1mg/g Hg in maternal hair			yes
			ave. 8	mean 0.60mg/g S. D. 7 0.60mg/g		of Memory and Learning 9 subtests, 3 indices:	Mean scores (n ¼393)	is associated with:			
				min 0.03mg/g		1. Visual Memory Index	88.3 7 13.2, Visual Memory	┐ 2.8 [┐ 5.0,┐ 0.6] Visual Memory		0.01	yes
				max 5.1mg/g		2. Verbal Memory Index	91.2 7 13.0, Verbal Memory	┐ 1.7 [┐ 3.9, 0.6] Verbal Memory		0.14	yes
				low, r 1.0 mg/g	└ 85	3. Learning Index	97.4 7 14.0, Learning	┐ 2.2 [┐ 4.6, 0.2] Learning		0.08	yes
				high, 4 1.0 mg/g	└ 15						
Ng et al. (2015)	Taiwan, China	166	2 yr	Cord blood Hg		Chinese Version of Child behavior	Results in ε4 APOE carriers,	β (SE), ε4 APOE carriers w/ high			
				mean 14.7mg/L		Checklist (100 items in 7 domains)	Scores for affected domains,	Hg vs. non-carriers w/ low Hg			
				S. D. 7 8.7mg/L		(only affected domains listed)	mean 7 S. D., (range)				
				median 12.0mg/L		Internalizing	12.0 7 7.3 (0┐ 32)	5.6 (2.1)		0.01	yes
				min 1.53mg/L		Externalizing	15.8 7 7.7 (0┐ 39)	4.1 (2.2)		0.06	yes
				max 47.1mg/L		Emotionally Reactive	3.1 7 2.5 (0┐ 11)	1.8 (0.7)		0.02	yes
				low, o 12.0mg/L	50	Anxious/Depressed	3.7 7 2.3 (0┐ 12)	2.1 (0.7)		o 0.01	yes
				high, Z 12.0mg/L	50	Aggressive Behavior	12.8 7 6.4 (O ┐ 32)	3.6 (1.8)		0.05	yes
						Total Problems	46.6 7 21.3 (6┐ 109)	14.3 (6.1)		0.02	yes
Jacobson et al. (2015)	Nunavik, Canada	279	11 yr	Cord blood Hg		Childhood IQ, using Wechsler	Full IQ Scores, mean 7 S. D.:	β, effect of cord Hg on IQ:	Relative Risk of IQ o 80		
				mean 21.8mg/L		Intelligence Scale for Children	Hg o 7.5 mg/L, IQ 95.8 7 11.7	┐ 0.17 [┐ 0.31,┐ 0.02]	17.2% if Hg Z 7.5 mg/L	0.021	yes
				S. D. 7 17.5 mg/L		4th Ed. (WISC-IV) and additional	Hg 4 7.5 mg/L, IQ 91.0 7 11.0		4.3% if Hg o 7.5 mg/L		
				min 1.0mg/L		culturally-adapted tests for			RR ¼4.0		
				max 99.3mg/L		verbal ability					
				low, o 7.5 mg/L	17						
				high, Z 7.5 mg/L	83						
Vejrup et al. (2016)	Norway	46,750	3 yr	Maternal Hg daily		Language Development,	Indices of Speech Development		OR's, high Hg vs. low Hg		
				dose in diet (est.)		rated on a 5-point scale for use	(best to worst ratings):				
				median 1.3mg		of grammar, full sentences,	Full sent., good gram, n ¼36,177				
				min 0.00mg		speaking clearly	Full sent., bad gram., n ¼8,719		1.01 [0.93, 1.10]		yes
				max 14.45mg			Short sentences, n ¼1,486		1.06 [0.88, 1.26]		yes
				high, 4 90th %ile,			Unintelligible Speech, n ¼102		2.22 [1.31, 3.72]		yes
				4 2.6mg	10		Did not talk/single words, n ¼266		1.04 [0.69, 1.57]		yes
						Ability to Communicate	Normal skills, n ¼44,757				
							Weak skills, n ¼595		1.33 [1.03, 1.70]		yes

Sidebar A–: The U. S. Reference Dose

The U. S. Environmental Protection Agency (EPA) establishes *Reference Doses* for toxic substances. A Reference Dose (RfD) is an estimated level of long-term exposure likely to pose no appreciable risk of adverse effects. RfDs are set by the USEPA to define tolerable exposures against which estimated actual exposures of populations can be compared to assess whether risk management measures may be called for.

In 2000 the USEPA set a RfD for MeHg (Rice et al., 2003). The agency began with the Faroes study (Grandjean et al., 1997), which associated several significant adverse cognitive outcomes with an average blood Hg level of 58 mg/L. Using that as a Benchmark Dose, EPA applied a 10-fold Uncertainty Factor (UF) to account for variation in individual sensitivity to toxic effects and other uncertainties in the risk assessment. The 10X UF produced a target blood Hg level of 5.8 mg/L, which a pharmacokinetic model associated with a dietary MeHg dose of 0.1 mg/kg of body weight per day. EPA thus set the RfD at 0.1 mg/kg/day.

That RfD can be used to estimate exposures at the RfD level for individuals of various body weights and various times. For example, the RfD for a 60-kg woman is 60 kg 0.1 mg/kg/day ¼6 mg/day. Since fish consumption advice typically focuses on weekly intake, MeHg intake at the RfD for one week for that standard 60-kg woman can be calculated as 42 mg (i.e., 7 days 6 mg/day).

The equilibrium blood Hg level associated with long-term intake at the RfD, 5.8 mg/L, is sometimes called the "reference level" of Hg in blood, a term used in this paper. A hair Hg level of 1.0 mg/kg corresponds approximately to a blood level of 5.8 mg/L, and is sometimes referred to as the "reference level" of Hg in hair.

from 3 days to 11 years. A meta-analysis of data from these studies has not been feasible, in large part because of this heterogeneity. The primary aims of Table 4 are to display the array of cognitive outcomes MeHg may affect and to compare levels of exposure associated with cognitive decrements in recent low-dose studies.

Several studies appear in both Tables 3 and 4; i.e., those studies observed both beneficial effects of maternal fish consumption and adverse effects of MeHg on the same cognitive outcomes in the same children. Those studies (and a few that looked for beneficial effects but found no statistically significant ones) generally controlled effectively for mutual confounding between benefits and harm, and their estimates of each effect have been adjusted to account for any confounding that was present; these methodological strengths enhance confidence in their quantitative results. For those studies in Table 4 that did not assess beneficial effects or adjust for mutual confounding, the cognitive decrements reported are, by default, net adverse effects.

Most studies in Table 4 divided their study populations into high- and low-MeHg exposure groups and compared outcomes for the two subsets. Gao et al. (2007), Lam et al. (2013) and Wu et al. (2014) each used the US reference blood Hg level, 5.8 mg/L (see Sidebar A) as their dividing line, and observed adverse effects in subjects with exposure 4 5.8 mg/L. Jacobson et al. (2015) divided their subjects at a cord blood Hg level of 7.5 mg/L, or slightly above the US reference level. Oken et al., 2005, 2008a used the 90th percentile of Hg exposure in their cohort as their dividing line; their 2005 high-Hg subjects had a hair Hg level of Z 1.2 mg/g, or slightly above the US reference hair Hg level of 1 mg/g. In 2008 they used maternal red blood cell Hg as their exposure index. NHANES data for the Northeast show a 90th percentile whole blood Hg level of 5.2 mg/L (Mahaffey et al., 2009), which is probably a reasonable estimate for the 90th percentile whole blood level (not reported) in this study. Sagiv et al. (2012) defined elevated exposure in their cohort as maternal hair Hg 4 1 mg/g.

Two studies, Lederman et al. (2008) and Orenstein et al. (2014), developed continuous dose-response functions spanning the full range of exposure in their cohort. Lederman et al.'s subjects had a mean maternal blood Hg level of 1.6 mg/L, while Orenstein et al.'s had a mean maternal hair Hg level of 0.60 mg/g. In both populations, the applicable US reference level fell within the exposure distribution, and higher-exposed individuals (those more likely to experience adverse outcomes) had blood or hair Hg values around or above those same reference levels. In summary, these nine studies all have associated adverse neurodevelopmental effects of MeHg exposure with exposures around or only slightly above about 5.8 mg/L in blood or 1 mg/g in hair, exposure levels that correspond roughly to the US RfD.

Two other studies in Table 4 associated cognitive deficits with prenatal MeHg exposures substantially below the US RfD. Jedrychowski et al. (2006) found developmental delays in children with a geometric mean cord blood Hg level of 1.05 mg/L and maternal GM 0.55 mg/L. Vejrup et al. (2016) associated delays in language development with maternal Hg doses above 2.6 mg/day, i.e., less than half the US RfD for a 60-kg woman. Though still low-dose studies, Suzuki et al. (2010) and Ng et al. (2015) each examined populations with higher fish intake and Hg exposure than in the US. The mean maternal hair Hg in Suzuki et al.'s Japanese cohort was 2.22 mg/g, while the median cord blood level in Ng's Taiwanese subjects was 12 mg /L; each value is about twice the corresponding US reference level.

3.5. Discussion: epidemiological evidence

The studies in Table 3 form a small but cohesive body of evidence that shows fairly convincingly that fish consumption during pregnancy has substantial benefits for children's cognitive development. Several issues remain unresolved. The strongest evidence is from the ALSPAC study, which has not been replicated, and may have controlled inadequately for some important confounding factors (Hattis, 2011). It is also unclear whether ALSPAC findings would apply for other populations with different seafood diets.

It is still somewhat uncertain whether benefits reach a plateau, although some analysts have concluded that they do. Specific constituents of fish that benefit prenatal cognitive development have also not been definitively identified. The n-3 PUFAs are known to be essential for brain development, and target intakes for n-3 s during pregnancy have been set (see DGA, 2015). Some clinical trials have reported beneficial effects of n-3 supplementation during pregnancy or lactation (see Cohen et al., 2005b), while other more recent trials have been negative (Makrides et al., 2009, 2010; Smithers et al., 2010, 2011). The studies in Table 3 for the most part reported seafood consumption (fish meals or grams per week during pregnancy), rather than quantifying n-3 intake. Thus significant uncertainty remains as to whether observed neurodevelopmental benefits can be attributed specifically to the n-3 content of seafood diets or just to "fish" as a package of nutrients.

Recent studies associating adverse effects on cognitive development with fish consumption during pregnancy, summarized in Table 4, mostly involve low-dose MeHg exposures, with dividing lines between high and low exposure clustered rather tightly around the US RfD. On the whole this evidence suggests that the RfD, which when established was thought to incorporate a 10-fold margin of exposure below the benchmark (i.e., clearly harmful) dose, may now be more accurately regarded as a dose level at or only slightly above which adverse effects can be observed.

In qualitative terms, several studies in Table 4 report neurodevelopmental deficits that cannot readily be converted to IQ scores (as was necessary for the meta-analyses in Table 2 and most benefit-risk models discussed in the Section 4); many of these

effects also were not previously linked to Hg. Some of these findings are supported by other evidence; for instance, Sagiv et al.'s 2012 report linking low-level MeHg exposure with Attention Deficit/Hyperactivity Disorder is similar to a study in a highly-exposed Inuit population associating a 4-fold increased risk of ADHD diagnosis with elevated prenatal MeHg exposure (Boucher et al., 2012). Three studies in Table 4 (two in China and one in Japan) have associated mildly impaired neuromotor functions in newborn infants with elevated maternal Hg exposure from fish consumption.

Several studies, starting with Murata et al.(2004), have associated low-level MeHg exposure with delayed transmission of nerve signals in the brain. Murata et al. examined auditory signals, while Boucher et al. (2014) and Ethier et al. (2012) linked MeHg with delayed transmission of signals in the visual cortex. Oken et al. (2005), Lam et al. (2013), Orenstein et al. (2014) and others have flagged visual memory development as a specific cognitive domain that may be particularly sensitive to disruption by MeHg exposure. On the whole, the literature now suggests that MeHg exposure can affect development of a wide variety of neurobehavioral and cognitive functions, some just beginning to be identified. There is no clear consensus as to what outcome or domain is "critical" or most sensitive to possible MeHg effects during brain development.

Both the quantitative magnitude of observed cognitive deficits and the fraction of the cohort with elevated exposure varied widely across the studies in Table 4, but the evidence as a whole suggests that MeHg effects are neither rare nor minimal and cannot be regarded as negligible compared to beneficial effects of fish intake. Decrements in relative performance on various outcome measures are greater than 25% of scoring scales in some studies; relative risks of adverse outcomes are up to 3–4 times as great in some higher-exposed subjects. These differences are as large as or in some cases greater than beneficial effects associated with fish consumption in Table 3.

The Hg doses associated with cognitive decrements in different studies also vary. The high fish and Hg intake of the Japanese, Hong Kong and Taiwan cohorts occur in only about 2% of US women, according to the FDA (2014a). The fraction of women with exposure above US Reference Levels (used as the definition of elevated exposure in several studies) varies from region to region in the US but averages about 4–5% (Mahaffey et al., 2009). In some subpopulations, such as Sagiv et al. (2012)'s New Bedford subjects or the Asian-American subset of Lederman et al.'s (2008) cohort, the fraction is much higher; 17% of Sagiv et al.'s mothers exceeded the hair reference level, and Lederman et al.'s Asian children had 4 times the average cord blood Hg level of non-Asians. The low dose (less than half the US RfD) associated with language delays in Norway is exceeded by about 17% of US women (FDA, 2014a). Overall, the evidence summarized in Table 4 associates frequently non-negligible cognitive deficits with prenatal MeHg exposure from fish intake. The doses involved are comparable to those routinely encountered by from a few percent to up to one in six US women of childbearing age.

There are many data gaps and differences and inconsistencies among studies, and many questions need more research. Some studies observed effects in very young subjects but not in the same cohorts when they were older (e.g., Jedrychowski et al., 2006, 2007; Oken et al., 2005, 2008a, 2014; Suzuki et al., 2010 and Tatsuda et al., 2014). In contrast, Lederman et al. (2008) found stronger associations in 3- and 4- year olds than in younger children, and Jacobson et al. (2015), Lam et al. (2013), Orenstein et al. (2014) and Sagiv et al. (2012), examined only older children but still associated deficits with prenatal exposure. Overall, the evidence suggests that effects of MeHg are highly domain-specific; as yet, neither IQ (often used to integrate results of different studies) nor any other outcome measure(s) can be defined as the most appropriate indicator of MeHg toxicity to the developing brain. While the existence and importance of variation among individuals in sensitivity to toxic effects has long been recognized, only recently has research begun to explore some specific genetic variations that affect susceptibility to MeHg (see Basu et al., 2014; Julvez and Grandjean, 2013; Julvez et al., 2013; Lee et al., 2010; Ng et al., 2013, 2015).

4. Benefit-risk models

The focus here is on models designed for or useful for comparing different seafood items to support consumer advice on which fish to choose or to avoid. Some benefit-risk models have also been used to estimate aggregate effects on neurodevelopment of all children, but that topic is outside the scope of this discussion. Four recent models are suitable for supporting seafood-choice advice. Their developers have combined epidemiologically-derived functions for benefits of nutrients and adverse effects of MeHg with seafood consumption scenarios to estimate net effects on cognitive development from eating different fish. Although the absolute values of the estimated outcomes differ widely based on differences in the data and assumptions fed into each model, the relative results for and rankings of different fish varieties offered by the models are generally quite informative and useful.

Benefit-risk models are valuable tools precisely because modelers can plug in any data and assumptions that seem reasonable and examine how those choices affect outcomes of interest. That same flexibility is also the most important limitation on modeling: Essentially, the results of modeling depend on subjective, often arbitrary choices, and the value of exploring multiple scenarios is offset by the need to interpret any quantitative model results cautiously.

Table 5 compares the projected net effects on neurodevelopment for 22 seafood varieties included in most or all models examined ("n.a." indicates that a particular variety was not included in that model.) Two of the models, FAO/WHO (2011) and FDA (2014a), include multiple versions and scenarios and appear in more than one column of the table. Three models expressed their results in terms of projected net effects on child IQ, while Ginsberg and Toal (2009) used Visual Recognition Memory (VRM) data from Oken et al.'s 2005 study, described in Tables 3 and 4 above. VRM, like IQ, is scored on a 100-point scale. Values in standard font in the table are net beneficial effects (i.e., IQ or VRM points gained), while values shown in parentheses and bold font (in parentheses) are net adverse effects (IQ or VRM points lost).

As the table makes clear, results of the different models vary a great deal. Ginsberg and Toal (2009) considered 16 popular seafood choices in Connecticut, USA and assumed a pregnant woman ate one 6-ounce (170-g) serving of one item per week. Their model projects effects that range from net gains of 10–12 VRM points for salmon, herring or anchovies, to net losses of 25–26 VRM points for swordfish and shark. Zeilmaker et al. (2013) used dose-response functions from Cohen et al., (2005a, (2005b, see Table 2) and assumed a "worst-case scenario" in which a woman ate 100 g of one seafood variety every day (700 g/week) before and throughout pregnancy to compare 33 popular European seafood items. Their model also projected a broad range of outcomes, from net gains of 0.5-2 IQ points for half a dozen fish varieties to net IQ losses of 8-12 IQ points for higher-Hg items like albacore tuna, pike and swordfish.

In contrast, the US FDA (2014a) and FAO/WHO (2011) models project net beneficial effects from consuming essentially any amount of any fish during pregnancy. The FDA modelers used a benefits slope derived using data from Daniels et al. (2004, see

Table 5
Net effects on neurodevelopment of consuming various popular seafood items while pregnant, as estimated by recent risk-benefit models.

	Benefit-Risk Models (cited publications)							
Authors & Date	Ginsberg and Toal (2009)	Zeilmaker et al. (2013)	FAO/WHO (2011)	FAO/WHO (2011)	FAO/WHO (2011)	FAO/WHO (2011)	FDA (2014a)	FDA (2014a)
Weekly Fish Intake	170 g/week	700 g/week	200 g/week	200 g/week	700 g/week	700 g/week	Optimal[a]	Optimal
Model Version			Central Est	Upper Bound	Central Est	Upper Bound	Fish	Omega-3 s
Outcome Measure	VRM	IQ	IQ	IQ	IQ	IQ	IQ	IQ
Seafood Item								
Sardines	n.a.	0	5.8	5.6	5.7	5.3	3.2	3.3
Salmon, Atlantic	12	2	5.8	5.6	5.7	5.3	3.2	3.3
Herring, Anchovies	10	0.5	5.8	5.6	5.7	5.3	3.2	3.3
Trout, Freshwater	5	0.3	5.8	5.6	5.7	5.3	3.2	3.2
Mackerel, Atlantic	n.a.	1	5.8	5.6	5.7	5.3	3.2	3.2
Shrimp	2	0	1.5	1.3	5.3	4.9	3.3	3.3
Pollock	1.2	n.a.	1.5	1.3	5.3	4.9	3.2	3.2
Clams/Mussels/ Oysters	n.a.	0	1.5	1.3	5.3	4.9	3.3	3.3
Tilapia	0.5	0.5	1.5	1.3	5.3	4.9	3.3	3.2
Catfish	n.a.	(┐ 1.5)	1.5	1.3	5.3	4.9	3.3	3.2
Flounder, Sole	1.4	(┐ 2)	1.5	1.3	5.3	4.9	3.2	3.1
Halibut	(┐ 4)	(┐ 4)	5.6	4.9	5	2.5	3	3.1
Tuna, Canned Albacore	(┐ 6)	(┐ 8)	4	3.3	3.4	0.9	2.8	3
Tuna, Canned Light	(┐ 2)	n.a.	n.a	n.a.	n.a	n.a	3.1	3
Tuna, Fresh	(┐ 8)	(┐ 8)	1.3	0.6	4.6	2.1	2.8	2.9
Sea Bass	(┐ 5)	n.a.	5.6	4.9	5	2.5	3	3.1
Cod	(┐ 2.5)	(┐ 1)	1.5	1.3	5.3	4.9	3.2	2.9
Lobster	(┐ 5)	n.a.	1.3	0.6	4.6	2.1	3.2	2.9
Pike	n.a.	(┐ 11)	1.5	1.3	5.3	4.9	n.a	n.a.
Swordfish	(┐ 25)	(┐ 12)	3	(┐ 0.5)	1.6	(┐ 10.5)	2	2.5
Shark	(┐ 26)	n.a.	3.6	1.9	3.7	(┐ 2.4)	2	2.4
Orange Roughy	n.a.	n.a.	0.9	(┐ 0.8)	3.3	(┐ 2.8)	2.6	0

[a] "Optimal" intake in the FDA model varies by seafood type; it is the weekly intake at which the excess of benefit over risk is maximum.

Table 3), and the adverse effects slope from Axelrad et al. (2007), shown in Table 2. The model has a version in which benefits are attributed to n-3 s, and one in which they are associated simply with "fish" as a nutrient package. MeHg reduces the size of beneficial effects in this model, but overall it predicts strong net beneficial effects for virtually all seafood varieties and likely consumption scenarios. The model identifies an optimal intake for each variety, defined as the weekly serving at which the excess of benefit over adverse effect is maximized. Optimal servings are all 8-10 ounces (227–284 g) per week in the fish-as-a-package version of the model, but range from 3 to 53 ounces 85-1,504 g) in the n-3 s version, reflecting the wide differences in n-3 content of seafood items. At optimal intakes in either version the model projects net IQ gains of 2.0-3.3 points for most seafood choices, with only small differences by type of fish.

The FAO/WHO model is largely based on an earlier iteration of FDA's model (FDA, 2009). The expert consultation that produced this modeling report sorted 96 seafood varieties into a 4┘ 4 matrix, stratified by n-3 and MeHg content, then projected beneficial and adverse effects on neurodevelopment using average n-3 and Hg values for each matrix cell. For example, herring, anchovies, Atlantic mackerel, trout, sardines and farmed Atlantic salmon all fall in the group with highest n-3 and lowest Hg content, and as the table shows, all are projected by the model to have identical large net beneficial effects on IQ.

The FAO/WHO modelers ran multiple scenarios, assuming a woman would eat 1, 2, 4 or 7 100-g servings of seafood per week while pregnant; for simplicity, they assumed she would always choose items from the same matrix cell. Two of those scenarios (200 and 700 g/week intake) are shown in Table 5. This model also includes two versions in which different slopes were used for the effect of prenatal MeHg exposure on child IQ; the table displays results using the "central estimate" slope (from Axelrad et al., 2007, see Table 2), and "upper bound" slope (from Cohen et al., 2005a, Table 2) for each intake scenario.

As Table 5 shows, the FAO/WHO model using the upper bound slope for Hg effects predicts net adverse effects on child IQ for a few highest-Hg fish at both consumption rates. But the FAO/WHO report focuses only on the central estimate results, concluding that "maternal fish consumption lowers the risk of suboptimal neurodevelopment in their offspring compared with the offspring of women not eating fish in most circumstances evaluated" (FAO/WHO, 2011).

Differences in results of these different models have led to parallel differences in seafood consumption advice from the modelers. Ginsberg and Toal (2009) and Zeilmaker et al. (2013) stressed both the benefits of maternal fish intake and the need to minimize prenatal MeHg exposure, and advised women to choose higher n-3, lower Hg seafood items. On the other hand, the US FDA and EPA relied almost exclusively on the FDA model when issuing updated draft joint fish consumption advice (FDA, 2014b); the advice urges pregnant women to eat more fish and treats seafood variety and Hg content as relatively minor concerns. The Dietary Guidelines Advisory Committee, advising HHS and USDA on the 2015 update to the Dietary Guidelines for Americans, cited only the FAO/WHO model as its basis for recommending that pregnant women increase their fish intake and that MeHg concerns should be de-emphasized (DGAC, 2015).

4.1. Discussion: benefit-risk models

The results in Table 5 not only differ greatly from each other, but some also differ strikingly from the epidemiological evidence, particularly on the risk side summarized in Table 4. At minimum, divergence between epidemiological observations and modeling results suggests that model results need to be interpreted cautiously. Because the FDA and FAO/WHO models are a proposed basis for US fish consumption advice, it is worth exploring in some detail why model results differ so much from each other and from epidemiological observations.

Table 6
Slopes for benefit and risk functions used in different models.

	FDA (2014a)	FAO/WHO Central Est.	FAO/WHO Upper Bound	Ginsberg and Toal (2009)	Zeilmaker et al. (2013)
	(IQ points)	(IQ points)	(IQ points)	(VRM points)	(IQ points)
DHA Benefit per 100 mg/day	2.8	4	4	2	0.13 (0.08, 0.18)
Benefit plateau?	Yes	Yes	Yes	No	No
Mercury Harm per Ig/g in hair	┐ 0.18	┐ 0.18	┐ 0.7	┐ 7.5	┐ 0.2 (0,┐ 1.5)

The simplest and most obvious reason for the disparities in model results in Table 5 is that the modelers in each case used different dose-response coefficients to estimate beneficial and adverse effects. Table 6 shows the slopes chosen for those coefficients in the different models. Slopes used in the models can also be compared with the slopes observed for various beneficial and adverse effects in epidemiological studies shown in Tables 3 and 4.

Zeilmaker et al. (2013) used slopes from Cohen et al., (2005a, 2005b, see Table 2); the slope for n-3 benefits, from clinical trials with supplements, was far smaller than the slope for MeHg effects derived from the Faroes, Seychelles and New Zealand studies. Thus their model projected modest net benefits for some species and larger net adverse effects for other varieties.

FDA (2014a) incorporated data shared with them by the ALSPAC research team into their model and estimated the slope for benefits to be 2.8 child IQ points gained per 100 mg/day of maternal n-3 intake. The FAO/WHO modelers had data from two ALSPAC reports, Daniels et al. (2004) and Hibbeln et al. (2007), and estimated a combined average slope of 4 IQ points gained per 100 mg/day of n-3 s. Both the FDA and FAO/WHO models include an assumption that beneficial effects plateau at about 12 ounces per week of fish intake; consequently, the maximum IQ gain possible from eating any amount of any fish is 3.3 points in the FDA model and 5.8 points in the FAO/WHO model.

To estimate adverse effects of MeHg, both the FDA model and the "central estimate" version of the FAO/WHO model used the slope from Axelrad et al.'s (2007) meta-analysis, ┐ 0.18 IQ points per 1 mg/g Hg in maternal hair (see Table 2). Given the very large slopes for beneficial effects and this much smaller slope for MeHg effects, these models' predicted excess of benefits over harm for essentially all plausible seafood intake scenarios is a foregone conclusion. The "upper bound" version of the FAO/WHO model uses a steeper slope, ┐ 0.7 IQ points per 1 mg/g hair Hg, Cohen et al.'s (2005a) "central estimate," (see Table 2), but there, too, the difference between slopes for beneficial and adverse effects is about 6-fold, and the model projects net IQ gains for consumption of all but a few very high-Hg fish.

Ginsberg and Toal's (2009) model uses dose-response data showing both strong benefits and strong adverse effects on VRM, measured in the same study by Oken et al. (2005). This model predicts large beneficial effects from eating high n-3, low-Hg fish, and very large adverse effects from eating high-Hg varieties. While this approach avoids uncertainties that arise when data from different studies are combined and converted to IQ, Oken et al.'s data set is quite small, and VRM may not adequately represent many other cognitive functions affected by seafood nutrients and/or MeHg. Ideally, other modelers will follow Ginsberg and Toal's approach and use data from other studies in Tables 3 and 4 to model the benefits and risks of various seafood choices.

A central question is whether any of these models, but especially the FDA and FAO/WHO models, are scientifically sound enough to be the primary basis for government fish consumption advice. Two concerns suggest that the models need to be critically re-examined before they are accepted as the basis for such important policy applications.

The first concern is the contrast between these models and the epidemiological evidence. Fig. 1 illustrates differences in MeHg doses associated with adverse effects by the two approaches. The RfD is shown (green line near the bottom) as a reference point. The FAO/WHO "central estimate" model (highest red line) predicts a net beneficial effect at a weekly swordfish intake of 700 g, containing 25 times the weekly MeHg RfD for a 60-kg woman, while the FDA model predicts zero net effect for almost the same swordfish intake, 681 g/week, containing 16 times the RfD (the models use different values for the MeHg content of swordfish.) In contrast, the much lower MeHg doses associated with cognitive deficits in 13 epidemiological studies fall within the blue-shaded box near the bottom of the figure.

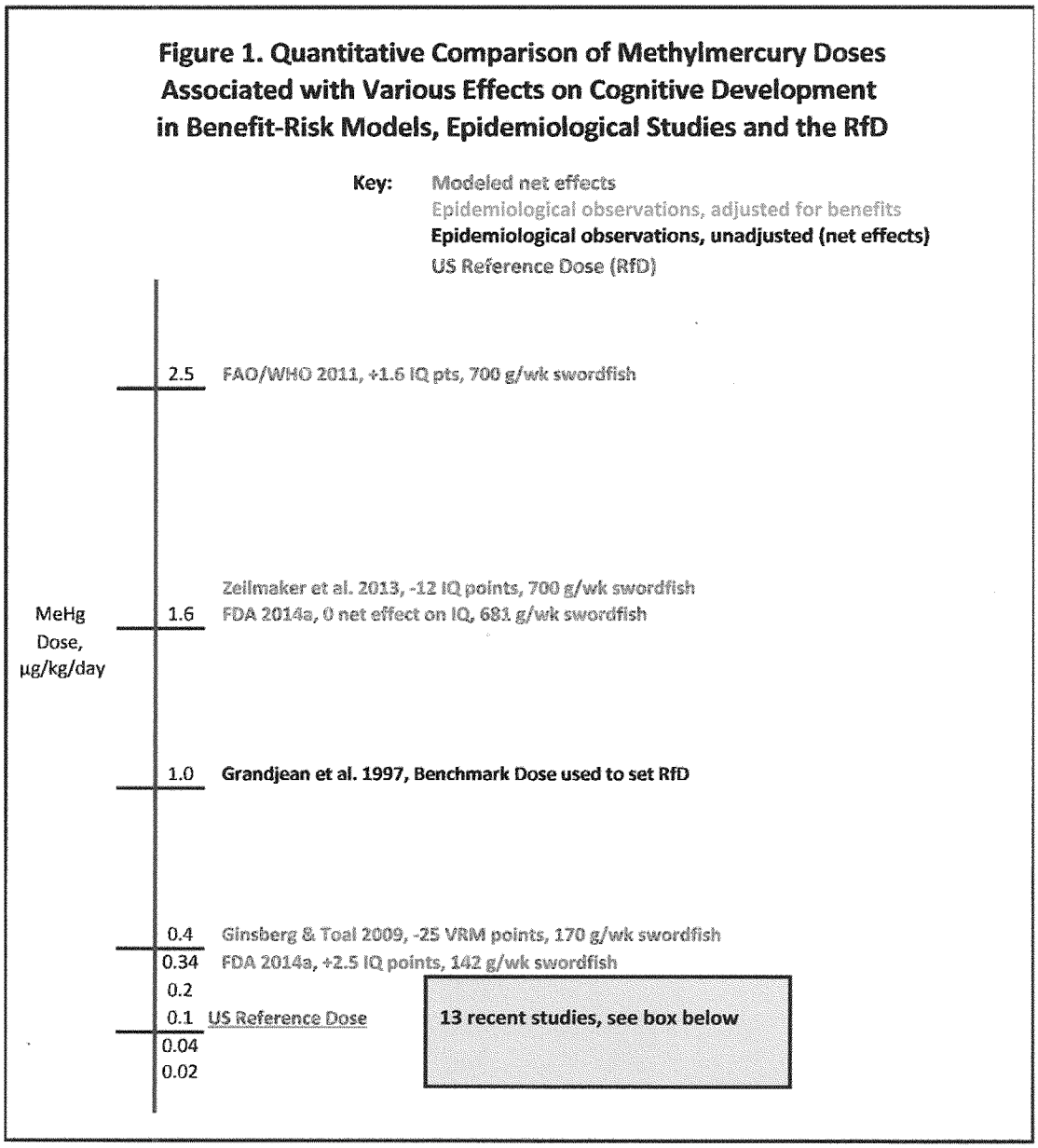
A second fundamental concern is that benefit-risk modeling is subject to unavoidable, well known limitations and uncertainties. Modeling benefits and risks of fish intake is still in its early evolution, with no consensus best approach yet, and all models reviewed here are subject to those limitations (see Sidebar B).

4.2. An integrated approach

Can differences between benefit-risk models and epidemiological data be reconciled, such that both types of evidence can be used in a balanced, integrated way to support fish consumption advice? Calibrating a model quantitatively against epidemiological evidence would support using the model's capacity to discriminate the relative benefits and risks of different seafood varieties to generate fish consumption recommendations consistent with risk and benefit estimates derived from recent epidemiology.

One way to inter-calibrate the two approaches is to replace dose-response functions used in the models with those generated in studies summarized in Tables 3 and 4, as Ginsberg and Toal (2009) have done with Oken et al.'s (2005) VRM data. This would require extensive effort and collaboration but should be encouraged. A second, simpler way to make models more congruent with epidemiology is to examine quantitative outcomes estimated by each, seeking common measures that can be compared to align model results with observed outcomes.

The FDA model (FDA, 2014a) identifies two points of particular interest on the net effects curve, illustrated generically in Fig. 2. At optimal intake, the excess of benefits over harm is maximized, and at crossover intake, the net effect is zero, i.e., the beneficial effects of fish nutrients are exactly cancelled out by the adverse effects of MeHg. Because modeled beneficial effects reach a plateau while adverse effects increase as fish and Hg intake rise, once past the optimal peak the net effects curve falls until it eventually crosses zero, and intakes greater than the crossover amount have net adverse effects. These concepts are clear, simple, reasonable, and major steps forward from vague generalities often used in the past (e.g., "the benefits outweigh the risks"). This is not to say the FDA model is established science; for instance, the assumption that benefits plateau, although perhaps sensible, is still uncertain, and many other critical open issues are enumerated in Sidebar B.



Recent studies showing adverse effects at/around the RfD/Reference Levels (see Table 4):

Gao et al. 2007, ≥ 5.8 µg/L Hg in cord blood
Jacobson et al. 2015, > 7.5 ug/L Hg in cord blood
Jedrychowski et al. 2006, > 0.80 µg/L blood
Lam et al. 2013, ≥ 5.8 µg/L Hg in cord blood
Lederman et al. 2008, continuous dose, GM 1.6 µg/L Hg in maternal blood
Ng et al. 2015, 12 µg/L blood
Oken et al. 2005, ≥ 1.2 µg/g Hg in maternal hair
Oken et al. 2008, > 5.2 µg/L Hg in maternal blood
Orenstein et al. 2014, continuous dose, mean 0.60 µg/g Hg in maternal hair
Sagiv et al. 2012, > 1. 0 µg/g Hg in maternal hair
Suzuki et al. 2010, 2.2 µg/g hair;
Vejrup et al. 2016, 2.6 µg/day dietary intake
Wu et al. 2014, ≥ 5.8 µg/L Hg in cord blood

Fig. 1. Quantitative comparison of methylmercury doses associated with various effects on cognitive development in benefit-risk models, epidemiological studies and the RfD. Mercury dose increases linearly along the Y axis from 0 to 4 2.5 mg/kg/day. The US Reference Dose (RfD), 0.1 mg/kg/day, is shown in green near the bottom. Model results are shown in red font, positioned by the mercury dose associated with the outcome indicated. Aside from the 1997 Faroes study, the epidemiological studies shown here examined doses that cluster around the RfD. Their positions on the figure fall within the blue-shaded box. The 13 individual studies are listed in the box below the figure, and study details are summarized in Table 4. Studies in blue font included adjustment for confounding by fish nutrients.

Sidebar B–: Critical Limitations and Uncertainties in the FDA and FAO/WHO Benefit-Risk Models

All benefit-risk models share fundamental, unavoidable limitations: gaps and uncertainties in available data, the need to make often arbitrary data choices and assumptions, the need to combine data from different studies and to convert diverse outcomes to common measures. The FDA and FAO/WHO models are by no means uniquely flawed, and are in many ways useful analytical tools. However, when considering the results of these models, these important limitations should be kept in mind:

- The slopes used for beneficial effects of fish consumption come only from the ALSPAC study, which has not been replicated.
- IQ is far from the only, and not necessarily the best, measure of cognitive benefits.
- The assumed plateau of beneficial effects, while plausible, is not fully supported by available studies and if it exists, the fish intake at which it occurs has not been well quantified.
- The question of whether n-3 intake adequately represents beneficial exposures is unresolved.
- The slopes used in both models for adverse effects of MeHg on cognitive development come from meta-analyses of data later shown to be substantially confounded by fish benefits, and therefore appear to underestimate adverse effects, perhaps by a wide margin.
- IQ is far from the only cognitive outcome affected adversely by MeHg, and may not be the most sensitive or most appropriate measure. Several studies in Table 4 suggest that other outcomes may be more sensitive.
- The FDA and FAO/WHO models are "blind" to effects not convertible to IQ.
- The models use average slopes for beneficial and adverse effects and treat all women and fetuses as average in sensitivity. No uncertainty factors are applied to account for variation among individuals in sensitivity to beneficial or adverse effects, and the results thus likely understate effects (perhaps in both directions, but probably in different individuals in each case) in sensitive sub-populations.
- FDA's exposure model predicts mean and 95th percentile blood Hg levels much lower than those observed in several of the studies in Table 4. The model does not accurately represent geographic and ethnic subpopulations (such as Asian-Americans) with high-fish diets and thus, significantly above-average MeHg exposure.
- The FDA's data on mercury levels in different fish are limited by small sample sizes for some species, and FDA's reported averages for many items differ from average levels in the same species reported elsewhere in the literature (see Karimi et al., 2012).

FDA's model includes two versions, fish-as-a-package and n-3 s, described in Table 5 and the accompanying text. This analysis uses the n-3 s version, not because it is certain that n-3 s are the driving beneficial nutrient in fish but because that version of the model draws distinctions among different fish and shellfish by incorporating a wider range of values for both beneficial and harmful components.

While the model is conceptually sound, its quantitative results need to be squared with recent epidemiological observations. That can be accomplished by comparing estimates generated by each approach of the "minimal adverse dose" (MAD) of MeHg, discussed earlier. The MAD can be estimated three ways:

(1) The RfD, described in Sidebar A, applies an uncertainty factor of 10X to a clearly harmful Benchmark Dose, BMD. By convention, the MAD is presumed to be below the BMD but higher than the RfD, which aims to provide a margin of exposure below the MAD. The RfD of 0.1 mg/kg/day corresponds to a blood Hg level of 5.8 mg/L and a hair level of about 1 mg/g. The RfD therefore indicates, rather imprecisely, that the MAD is associated with more than 5.8 mg/L Hg in blood or 1 mg/g Hg in hair, but less than 10X those exposures.
(2) An epidemiology-derived MAD (eMAD) can be estimated from data summarized in Table 4. Those 13 studies associated adverse effects on cognitive development with prenatal MeHg doses at or slightly above or below the RfD. Overall this evidence places the eMAD very close to the RfD, i.e., considerably lower than the MAD was perceived to be when the RfD was set in 2000. For this analysis, the eMAD is defined as equal to the RfD.
(3) MADs are also estimated by the FDA model. The "crossover" point in Fig. 2 is the intake of any fish (and thus the MeHg dose) at which beneficial effects and adverse effects exactly cancel out; intakes slightly greater than the crossover amount have net adverse effects. This exposure point is conceptually analogous to MADs derived from other approaches, i.e., it is a model-derived MAD (mMAD).

Using mMADs from the FDA model and the eMAD described in (2) above as starting points, the FDA model's crossover serving sizes were re-calculated to bring them more in line with observations from population studies.

The data and calculations used for this recalibration analysis are displayed in Table 7. FDA estimated crossover intakes for 47 seafood categories (FDA, 2014a, Table V-8). The table lists 60 varieties, because FDA lumped similar species together—for example, haddock, hake and monkfish are a single category in FDA's database—while each variety is listed individually in Table 7.

5. Results

As Table 7 shows, FDA's crossover intakes range from 16 ounces (454 g) per week for Gulf tilefish to 3,364 ounces (95,454 g) per week for scallops, and for 43 of the 60 items, crossover intake exceeds 100 ounces/week. Crossover intake reflects the modeled net effect (on child IQ) of n-3 benefits and MeHg adverse effects; however, these intakes are driven primarily by MeHg content of the fish, because benefits plateau at about 8-12 ounces of fish per week on average (full range, 3-53 ounces), while Hg effects increase linearly with dose until benefits are cancelled out and net adverse effects appear.

FDA data on the MeHg content of each seafood item (FDA, 2014a, Table V-8) were used to calculate MeHg doses in crossover servings or mMADs, also shown in Table 7, which range from 514 to 891 mg/week (mean 671 mg/week). The mMADs vary from one fish type to another because amounts of n-3 s, which affect the benefits peak and thus the vertical distance from optimal to crossover intake in Fig. 2, also vary widely among seafood types.

FDA's crossover servings were then recalculated using the eMAD. Since the eMAD is equal to the RfD and weekly MeHg exposure at the RfD for a 60-kg woman is 42 mg, the weekly mMAD for each seafood item was divided by 42 mg, yielding the number of eMADs in each crossover serving. Serving sizes were then divided by the number of eMADs they contain to calculate servings for each seafood item, shown in the next-to-last column of the table,

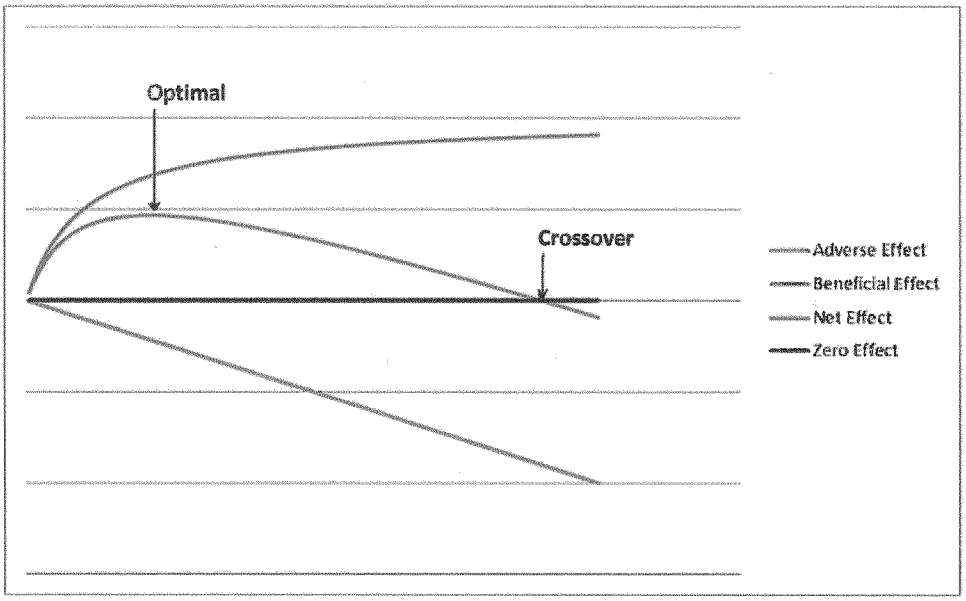


Fig. 2. FDA's Generic Benefit-risk Model. The figure (from Spiller, 2014) depicts the interaction between beneficial and harmful effects on cognitive development for any seafood variety consumed during pregnancy. Fish intake increases along the X axis; changes in IQ increase or decrease along the Y axis, with 0 effect at the X axis. Beneficial effects (the uppermost, green line) increase steeply at low fish intakes then level off, because the model assumes these effects reach a plateau. Methylmercury adverse effects (the bottom, red line) increase linearly with dose, in proportion to the amount of fish eaten. Positive effects (IQ gain) and adverse effects (IQ loss) combine to produce net IQ effects, shown by the central, blue curve.

that contain 1 eMAD of MeHg. They range from 1 ounce for Gulf tilefish to 210 ounces for scallops.

One further adjustment was needed. From a risk-management perspective, exposure at the eMAD is probably not acceptable. Estimates of benefits and risks are not precise enough to lay to rest the reasonable concern that exposure around the RfD/eMAD might fall within the range of net adverse effects, at least for sensitive individuals. In addition, the "crossover" point is where nutritional benefits are cancelled out by MeHg harm; a preferable goal of policy would be to aim for intakes whose benefits exceed possible harm by a significant margin. Consumer advice should therefore aim to keep MeHg intake well below the RfD/eMAD, a sensible precautionary approach supported by a fairly broad consensus.

How and where to draw the line below the RfD/eMAD is an admittedly subjective expert judgment with a substantial value component. An uncertainty factor of 2 was applied at this step, with the following rationale: A 2X exposure margin below the eMAD provides some cushion against uncertainties, yet most of the serving sizes that contain 0.5 eMAD fall well within the range of typical intakes. Thus advice based on these results should encourage, not discourage, consumption of the large majority of seafood items.

Final adjusted serving sizes containing 0.5 of the RfD/eMAD are shown in the last column of Table 7, and color-coded to support consumption advice. Because risk management for MeHg exposure from fish depends primarily on risk communication (i.e., consumer advice), the ultimate product of this analysis is a seafood choice chart, Fig. 3. The criteria used to generate the chart from the last column of Table 7 are shown in Table 8. The 60 seafood items fall into five choice categories based on recommended frequency of consumption: Eat All You Like (19 varieties); Eat Often (14 varieties); Eat Occasionally (11 varieties); Eat Rarely (11 varieties); and Do Not Eat (5 varieties).

6. Conclusions and final discussion

Wide differences between results of benefit-risk models and health outcomes observed in epidemiological studies have complicated the task of crafting consistent, science-based fish consumption advice. Many risk communicators have found that when the public perceives that experts cannot agree, consumers tend to be risk-averse. This may be especially true for pregnant women, a notably risk-averse subpopulation, who have not significantly increased fish consumption despite advice from many sources that they should do so. One primary reason for this dilemma seems to be that most consumers do not have enough information about differences in the comparative benefits and risks of seafood choices (Lando and Lo, 2014; Oken, 2014; Oken et al., 2013).

Conflicts between modeling and epidemiology can also undermine the scientific foundations of government fish-consumption advice. Simply put, it is not a sound policy approach to choose to believe a model and ignore the epidemiological evidence, as the US FDA and EPA have recently proposed to do (FDA, 2014b). Disparities between models and epidemiology need to be resolved, so that both types of evidence can be integrated to provide more comprehensive, coherent and scientifically defensible advice.

Some such integration may occur if the research community continues the iterative improvement of benefit-risk models, replacing older dose-response coefficients derived from confounded data used in most models to date with data from recent epidemiological studies.. However, this approach requires extensive resources and collaboration and is likely to proceed slowly, if at all.

A simpler approach, taken here, is to try to align FDA's model results with recent epidemiological evidence. This analysis leads to recommended weekly servings for 60 seafood varieties ranging from 0.5 to 105 ounces. Those serving sizes reflect biologically meaningful differences in the n-3 and MeHg contents of different fish and shellfish, which underlie parallel differences in FDA's crossover servings used as the starting points. The final serving sizes take advantage of the model's discriminatory ability but are also consistent with recent epidemiology-based risk and benefit estimates.

The proposed updated FDA/EPA advice (FDA, 2014b) includes a recommendation that pregnant women eat 8–12 oz of fish per week. Women are advised to choose "lower-Hg" fish, but only a

Table 7
FDA's crossover servings adjusted to generate recommended servings.

Seafood Item	Hg, µg/g	Crossover Serving, Oz/week,	Crossover Serving, g/week,	Hg dose in Serving, µg/week	MADs in Crossover Serving	Adjusted Serving, Oz/week	Half of Adjusted Serving
Tilefish, Gulf	1.45	16	454	658	16	1	0.5
Swordfish	1.00	24	681	681	16	1.5	0.75
Shark	0.98	24	681	667	16	1.5	0.75
King Mackerel	0.73	32	908	663	16	2	1
Orange Roughy	0.57	0	0	0	0	0	0
Grouper	0.46	51	1,447	666	16	3.2	1.6
Fresh Tuna	0.39	60	1,703	664	16	3.8	1.9
Spanish Mackerel	0.37	64	1,816	672	16	4	2
Sablefish	0.37	64	1,816	672	16	4	2
Bluefish	0.35	64	1,816	636	15	4.3	2.2
Canned Albacore Tuna	0.35	67	1,901	665	16	4.2	2.1
Pacific Croaker	0.30	78	2,213	664	16	4.9	2.5
Lingcod	0.29	82	2,327	675	16	5.1	2.6
Scorpionfish	0.29	82	2,327	675	16	5.1	2.6
Sea Trout	0.26	91	2,582	671	16	5.7	2.9
Sea Bass	0.25	95	2,696	674	16	5.9	2.9
Halibut	0.22	95	2,696	593	14	6.8	3.4
Carp	0.17	139	3,944	670	16	8.7	4.4
Buffalofish	0.17	139	3,944	670	16	8.7	4.4
Snapper	0.16	147	4,171	667	16	9.2	4.6
Porgy	0.16	147	4,171	667	16	9.2	4.6
Sheepshead	0.16	147	4,171	667	16	9.2	4.6
Ocean Perch	0.15	157	4,455	668	16	10	5
Rockfish	0.15	157	4,455	668	16	10	5
Mullet	0.15	157	4,455	668	16	10	5
Skate	0.14	172	4,881	683	17	10	5
Canned Light Tuna	0.13	196	5,562	723	17	12	6
American Lobster	0.11	214	6,072	668	16	13	7
Spiny Lobster	0.11	214	6,072	668	16	13	7
Atlantic Tilefish	0.11	214	6,072	668	16	13	7
Whitefish	0.10	235	6,668	667	16	15	8
Cod	0.09	229	6,498	585	14	16	8
Chub Mackerel	0.09	268	7,605	684	16	17	9
Atlantic Croaker	0.08	302	8,569	686	16	19	10
Sole & Plaice	0.08	310	8,796	704	17	18	9
Flounder	0.08	310	8,796	704	17	18	9
Squid	0.07	336	9,534	667	16	21	11
Haddock	0.07	351	9,960	697	17	21	11
Hake	0.07	351	9,960	697	17	21	11
Monkfish	0.07	351	9,960	697	17	21	11
Smelt	0.07	351	9,960	697	17	21	11
Crabs	0.06	374	10,612	636	15	25	13
Butterfish	0.06	406	11,520	691	16	25	13
Anchovies	0.05	471	13,365	668	16	29	15
Herring	0.05	471	13,365	668	16	29	15
Shad	0.05	471	13,365	668	16	29	15
Atlantic Mackerel	0.05	481	13,648	682	16	30	15
Atka Mackerel	0.05	481	13,648	682	16	30	15
Pollock	0.04	636	18,047	722	17	37	19
Crawfish	0.03	693	19,664	589	14	50	25
Freshwater Trout	0.03	736	20,884	627	15	49	25
Salmon (all types)	0.02	1,080	30,645	613	15	72	36
Clams	0.02	1,024	29,056	581	14	73	37
Sardines	0.02	1,177	33,397	668	16	74	37
Catfish	0.02	1,385	39,299	786	19	73	37
Pangasius	0.02	1,385	39,299	786	19	73	37
Oysters & Mussels	0.02	1,570	44,549	891	21	75	38
Tilapia	0.01	1,811	51,387	514	12	151	76
Shrimp	0.01	2,141	60,751	608	14	153	77
Scallops	0.007	3,364	95,454	668	16	210	105

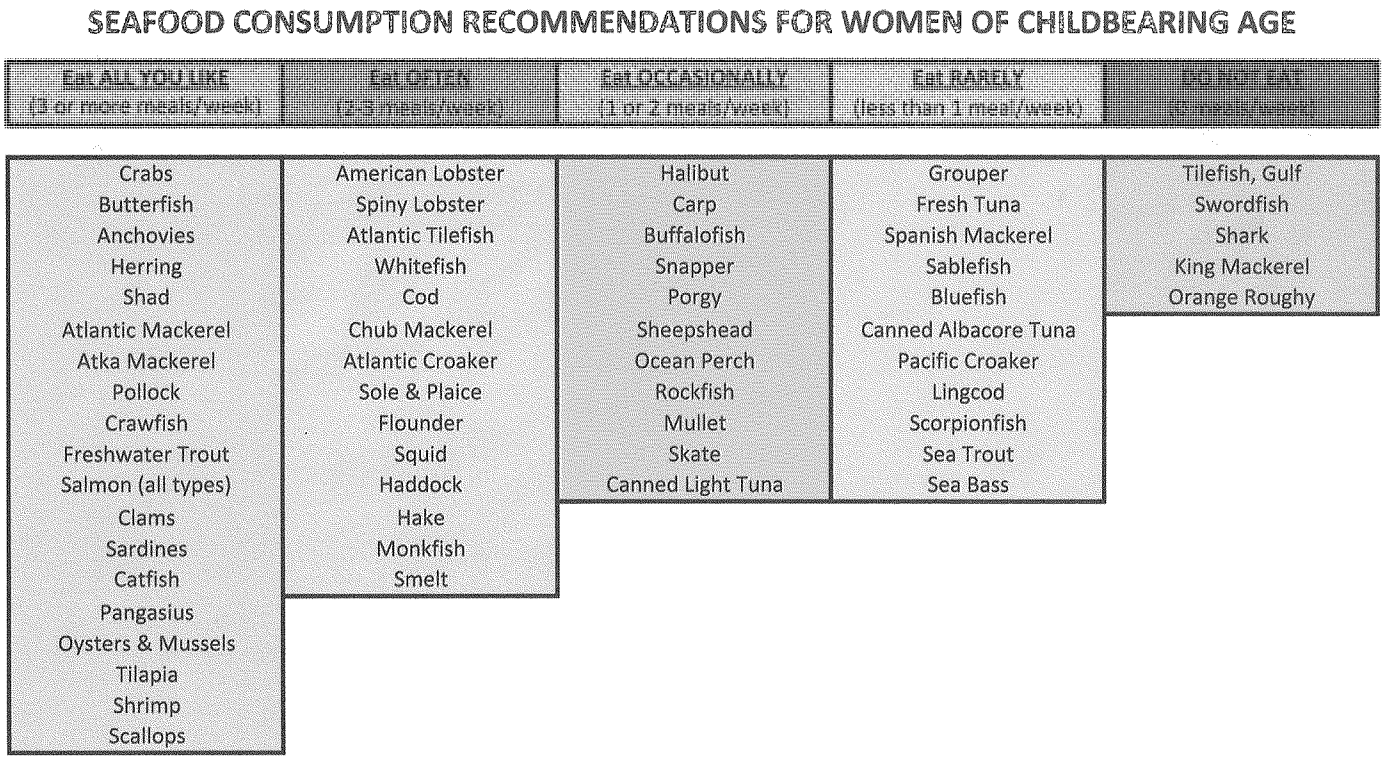


Fig. 3. Seafood Choice Chart. Serving sizes for 60 seafood items shown in the final column of Table 7 were sorted into five categories, based on how often they can be consumed by a pregnant woman, using the criteria and color codes in Table 8. The chart headings indicate meals per week, rather than ounces per week, using 4–6 ounces as an approximate standard serving size.

Table 8
Sorting criteria used to create the chart in Fig. 3.

If the adjusted model says a woman can eat	The item goes in this category	And the color code is
≥ 12 ounces per week	Eat All You Like	Blue
6-12 ounces per week	Eat Often	Green
3-6 ounces per week	Eat Occasionally	Yellow
1-3 ounces per week	Eat Rarely	Orange
< 1 ounce per week	Do Not Eat	Red

few items are listed as "lower-Hg choices," and they are all top-selling items in the US seafood market. With no statements to suggest otherwise, it appears that any item not on the FDA/EPA's "do not eat" list (four very high-Hg varieties) is "lower-Hg" and thus an equally acceptable choice. This advice offers little practical guidance for consumers and is unlikely to change either fish consumption patterns or Hg exposure (Groth, 2015).

In 2015 the Dietary Guidelines Advisory Committee recommended to HHS and USDA that updated 2015 guidelines for fish consumption should simply promote increased seafood intake and de-emphasize concerns about MeHg (DGAC, 2015). However, the published 2015 Dietary Guidelines for Americans (DGA, 2015) take a different approach, advising pregnant women to increase consumption of high-n-3, low-Hg seafood varieties and listing nine choices that fit those criteria. While this advice can help pregnant women choose wisely, the 2015 DGA are silent on the benefits and risks of the vast majority of items consumers encounter in the seafood market.

In contrast to the rather limited advice currently available from US agencies, Fig. 3 sorts 60 seafood items into five distinct categories, showing how often each can be eaten by pregnant women. The categories are color-coded and ranked based on relative benefit-risk outcomes in the FDA model, not just on MeHg content, an important distinction. While it remains to be seen whether a robust list of recommended choices will increase fish consumption, possible impacts of following this fish-choice advice on MeHg exposure can be readily examined.

Table 9 uses market share and Hg data from FDA (2014a) to estimate the relative contributions of individual seafood items to the total amount of MeHg in the US seafood supply, and thus, indirectly, to MeHg exposure from commercially-caught seafood among American women of childbearing age. This table updates an earlier analysis (Groth, 2010).

Table 9 shows that the blue, "eat all you like" category of Fig. 3 makes up 60% of the US seafood market, and the green, "eat often" category accounts for another 12%. Nine of the 11 most popular US fish and shellfish varieties (unshaded boxes) fall in those two groups. Women who follow the advice in Fig. 3 will therefore find many widely available, familiar choices recommended, and relatively few changes in consumer behavior would be required for women to "choose wisely" at the seafood market.

On the other hand, the red, "do not eat" and orange, "eat rarely" categories combined make up only 6% of the US seafood market (and more than half of that is one product, canned albacore tuna), but provide more than 40% of total MeHg exposure. If women cut back on consuming these varieties, market impacts, except on canned tuna (see below), should be minimal. FDA/EPA advisories have long warned women not to eat Gulf tilefish, swordfish, shark and king mackerel (see FDA, 2004), and in issuing proposed updated advice (FDA, 2014b) the agencies sought comments on whether to add orange roughy to that list. The red category in Fig. 3 is thus almost perfectly congruent with current and proposed FDA/EPA advice.

Fig. 3 differs most notably from recently issued and proposed

Table 9
Contributions to total mercury in the US seafood supply by individual seafood varieties as sorted in Fig. 3.

Seafood Item	Mercury µg/g	Market Share, %	Hg Input Factor	Percent of Total Hg
Blue Category				
Crabs	0.060	1.57	0.0942	1.462
Butterfish	0.060	0.06	0.0036	0.056
Anchovies, Herring & Shad	0.050	1.55	0.0775	1.203
Mackerel, Atlantic & Atka	0.050	0.57	0.0285	0.443
Pollock	0.040	9.27	0.3708	5.758
Crayfish	0.030	0.53	0.0159	0.247
Freshwater Trout	0.030	0.74	0.0222	0.345
Salmon (all types)	0.020	9.14	0.1828	2.839
Clams	0.020	0.98	0.0196	0.304
Sardines	0.020	0.64	0.0128	0.199
Catfish & Pangasius	0.020	6.16	0.1232	1.913
Oysters & Mussels	0.020	0.59	0.0118	0.183
Tilapia	0.010	7.22	0.0722	1.121
Shrimp	0.010	20.16	0.2016	3.130
Scallops	0.010	0.70	0.0070	0.109
Category Totals:	**0.021**	**59.88**	**1.2437**	**19.312**
Green Category				
American Lobster	0.110	0.72	0.0792	1.230
Spiny Lobster	0.110	0.46	0.0506	0.786
Atlantic Tilefish	0.110	0.01	0.0011	0.017
Whitefish	0.100	0.16	0.0160	0.248
Cod	0.090	4.29	0.3861	5.996
Chub Mackerel	0.090	0.09	0.0081	0.126
Atlantic Croaker	0.080	0.21	0.0168	0.261
Flounder, Sole & Plaice	0.080	2.77	0.2216	3.441
Squid	0.070	1.29	0.0903	1.402
Haddock, Hake & Monkfish	0.070	2.20	0.1540	2.391
Smelt	0.070	0.05	0.0035	0.054
Category Totals:	**0.084**	**12.25**	**1.0273**	**15.952**
Yellow Category				
Halibut	0.220	0.48	0.1056	1.640
Carp & Buffalofish	0.170	0.04	0.0068	0.106
Snapper, Porgy, & Sheepshead	0.160	0.43	0.0688	1.068
Perch, Rockfish & Mullet	0.150	0.83	0.1245	1.933
Skate	0.140	0.40	0.0560	0.870
Canned Light Tuna	0.128	8.87	1.1354	17.632
Category Totals:	**0.135**	**11.05**	**1.4971**	**23.249**

Table 9 (continued)

Orange Category				
Grouper	0.460	0.15	0.0690	1.071
Fresh/Frozen Tuna	0.390	1.29	0.5031	7.813
Spanish Mackerel	0.370	0.03	0.0111	0.172
Sablefish	0.370	0.19	0.0703	1.092
Bluefish	0.350	0.06	0.0210	0.326
Canned Albacore Tuna	0.350	3.61	1.2635	19.621
Pacific Croaker	0.300	0.01	0.0030	0.046
Ling Cod & Scorpionfish	0.290	0.02	0.0058	0.090
Saltwater Trout	0.260	0.01	0.0026	0.040
Saltwater Bass	0.250	0.01	0.0025	0.039
Category Totals:	**0.363**	**5.38**	**1.9519**	**30.310**
Red Category				
Gulf Tilefish	1.450	0.02	0.0290	0.450
Swordfish	1.000	0.37	0.3700	5.746
Shark	0.980	0.06	0.0588	0.913
King Mackerel	0.730	0.04	0.0292	0.453
Orange Roughy	0.570	0.30	0.1710	2.655
Category Totals:	**0.833**	**0.79**	**0.6580**	**10.217**

government advice by listing 33 specific recommended choices (the blue and green categories), and by providing tiered, nuanced cautionary advice to limit—not eliminate—intake of 22 other choices (the yellow and orange categories).

Table 9 shows (grey-shaded boxes) the 10 largest sources of MeHg in the US seafood supply. These top 10 items combined account for 75% of US MeHg exposure from commercially-caught seafood. Intuitively, if women ate less of these 10 items, their average exposure to MeHg should decrease. It is actually not quite that simple—5 of the top 10 sources are in fact low or about average in MeHg content, but are top sources because of their large market shares. On the other hand, the three varieties of tuna in Table 9 (canned albacore, canned light and fresh/frozen) are the three largest sources of Hg exposure by a wide margin; combined, these tuna varieties account for over 45% of the Hg total shown in Table 9. If the average American woman is to reduce her MeHg exposure while she also eats more fish, eating less tuna and less of a few other varieties like swordfish, shark and orange roughy, and eating more of low-Hg varieties like salmon, shrimp and herring, should help achieve both goals.

In 2009 FDA estimated that the market-weighted overall average Hg level in the US seafood supply was 0.086 mg/g (FDA, 2009). By 2014, the estimate had dropped to 0.071 mg/g (FDA, 2014a). This trend reflects gains in market share by low-Hg varieties such as salmon, shrimp, catfish and tilapia in recent years, while consumption of larger, predatory, higher-Hg varieties such as swordfish and canned tuna has been declining steadily.

The market-weighted average Hg level of seafood items in the blue column of Fig. 3 is 0.021 mg/g, while the average for the green column is 0.084 mg/g; combined, the average Hg content of the two columns is 0.031 mg/g. If women chose the vast majority of their seafood meals from the blue and green categories, the average Hg content of an average woman's fish meals could be reduced to less than half of the current average for the US seafood supply as a whole. In that scenario, even a woman who doubled her fish consumption could simultaneously markedly reduce her MeHg exposure.

In summary, a few high-Hg seafood varieties account for a very large share of US exposure to MeHg. Consumption advice that guides women away from those varieties, and toward lower-Hg, high n-3 choices, can both foster increased fish consumption and its attendant benefits and reduce MeHg exposure. To meet both goals, advice needs to draw clear distinctions among fish and shellfish varieties, identifying a lengthy list of choices with favorable benefit-risk profiles and cautioning women to limit or avoid consuming other varieties with less favorable profiles. Fig. 3 provides one template for such advice.

This approach has the advantages of simplicity and transparency; some might argue that it is too simple, even simplistic. The step-by-step analysis laid out here can be compared with the complexity and frequent lack of transparency of benefit-risk models. Moreover, while agencies relying on the FDA and FAO/WHO models as foundations for advice have largely failed to examine critically the dozens of data gaps, uncertainties and value judgments inherent in the models, many of those limitations are explicitly enumerated in Sidebar B here. Since the starting point is FDA's model, the results of this analysis are subject to those caveats. A key value judgment embedded in adjustments to the model is also explicit.

This approach is limited to examining the well-documented trade-offs between n-3 benefits and MeHg risks for prenatal cognitive development. Other nutrients and contaminants in seafood may affect those and other developmental outcomes, and fish consumption has large cardiovascular benefits that are outside the

scope of the analysis.

In this context, no method for crafting advice is perfect, and iterative improvement should be the goal. The objective of public health policy is to optimize benefits and minimize risks of fish consumption by pregnant women (or to maximize the excess of benefits over risks) for individuals to the extent possible, and for society in general. It is not feasible to tailor fish consumption advice precisely enough to guarantee optimal outcomes for individual consumers. More modest and appropriate goals are to make the best sense possible of the available evidence, to avoid trying to be more definitive than science allows, and to offer general guidance that is reasonably likely to promote both increased benefits and reduced risks.

The integration of modeling with epidemiological evidence developed here comes closer to those objectives than advice based on either approach by itself, and thus, offers a broader and potentially sounder scientific foundation than the proposed basis for recently drafted government advice on this topic. In particular, by calibrating the FDA model against the epidemiological results for MeHg exposures, this analysis tries to resolve the dose-response disparity on the risk side of the equation, arguably the most problematic shortcoming of the model.

Fig. 3 is certainly not the last word on the subject; there is no one "best" way to craft and present seafood consumption advice. But it may contribute to a national conversation on how public health policy can optimize both of these vital objectives.

Conflict of interest declaration

The author declares he has no conflicts of interest.

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To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Bigler, Jeff
Sent: Wed 7/8/2015 5:01:45 PM
Subject: Re: SOLICITING INPUT: dual websites for seafood advice

Yes.

□ □ □ □ □

On Jul 8, 2015, at 1:00 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

> Sorry, I was rushing and wasn't clear. I am all for having our website still. The question is, do we also want our website clearly shown on the chart with FDA's? I am thinking yes, but soliciting your opinions.
>
> **From:** Bigler, Jeff
> **Sent:** Wednesday, July 08, 2015 12:59 PM
> **To:** Larimer, Lisa
> **Cc:** Wathen, John
> **Subject:** Re: SOLICITING INPUT: dual websites for seafood advice
>
> We have - and have always had - our own advisory website. FDA's site often changes and can be hard to find. Plus we have our own group of stakeholders and "followers" who will continue to look for the advice on our site.
>
> On Jul 8, 2015, at 12:43 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:
>
> > We can't get a .gov website for our fish advice. It seems to makes sense for each agency then to have a website for this. We want our website to be listed on the chart too, yes? Or would that be confusing to the public?
> >
> > **From:** Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
> > **Sent:** Tuesday, July 07, 2015 12:53 PM
> > **To:** Larimer, Lisa
> > **Subject:** RE: separate domain for seafood advice

Makes sense. So we should put both of them on our chart?

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, July 07, 2015 12:38 PM
To: Natanblut, Sharon
Subject: RE: separate domain for seafood advice

That's too bad. I think a second choice would be for us to do twin sites: www.fda.gov/fishadvice and www.epa.gov/fishadvice - I'm pretty sure I can get that through pretty easily on our end.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, July 07, 2015 8:51 AM
To: Larimer, Lisa
Subject: FW: separate domain for seafood advice

Please see below regarding establishing a URL. Still checking on things.

From: Das, Sharmi
Sent: Monday, July 06, 2015 3:34 PM
To: Natanblut, Sharon
Cc: Herndon, Michael L
Subject: separate domain for seafood advice

Hi Sharon, Mike and I talked with Chris Mulieri today about establishing a second level domain (like hhs.gov) for EPA/FDA seafood guidance. Here's what we discussed:

1. There's a moratorium on .gov sites. The last HHS web council meeting confirmed that the moratorium is still in place.
2. Only way we can get permission to do is justify with strong reasons for a separate domain. The request must be approved by head of ASPA and HHS CIO. CTP did one a few years back BeTobaccoFree.gov

http://betobaccofree.hhs.gov/index.html , it's a full-blown site with lots of content and social media campaign, etc.

3. Problems to consider with establishing a separate URL at this time is that people are already used to going to FDA or EPA websites for draft guidance on seafood, therefore search engine optimization will be lost. Content must be robust in order to stand up a separate domain and attract people to this new site.
4. A catchy alias like "seafoodadvice from FDAEPA" may be an alternative.

Mike and I are happy to chat with you more about this. Let us know if you have any questions. Thanks.

s.

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Fri 11/20/2015 8:39:10 PM
Subject: Can you take a quick look at this?
Ex. 5 - Deliberative Process for fish advice-112015.docx

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Bigler, Jeff
Sent: Wed 7/8/2015 4:58:40 PM
Subject: Re: SOLICITING INPUT: dual websites for seafood advice

We have - and have always had - our own advisory website. FDA's site often changes and can be hard to find. Plus we have our own group of stakeholders and "followers" who will continue to look for the advice on our site.

On Jul 8, 2015, at 12:43 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

> We can't get a .gov website for our fish advice. It seems to makes sense for each agency then to have a website for this. We want our website to be listed on the chart too, yes? Or would that be confusing to the public?
>
> **From:** Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
> **Sent:** Tuesday, July 07, 2015 12:53 PM
> **To:** Larimer, Lisa
> **Subject:** RE: separate domain for seafood advice
>
> Makes sense. So we should put both of them on our chart?
>
> **From:** Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
> **Sent:** Tuesday, July 07, 2015 12:38 PM
> **To:** Natanblut, Sharon
> **Subject:** RE: separate domain for seafood advice
>
> That's too bad. I think a second choice would be for us to do twin sites: www.fda.gov/fishadvice and www.epa.gov/fishadvice - I'm pretty sure I can get that through pretty easily on our end.
>
> **From:** Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
> **Sent:** Tuesday, July 07, 2015 8:51 AM
> **To:** Larimer, Lisa
> **Subject:** FW: separate domain for seafood advice

Please see below regarding establishing a URL. Still checking on things.

From: Das, Sharmi
Sent: Monday, July 06, 2015 3:34 PM
To: Natanblut, Sharon
Cc: Herndon, Michael L
Subject: separate domain for seafood advice

Mike and I are happy to chat with you more about this. Let us know if you have any questions. Thanks.

s.

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Jones, William
Sent: Tue 5/12/2015 8:14:58 PM
Subject: RE: 4th FDA-EPA meeting on fish advice

I'm waiting to hear back on that.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, May 12, 2015 1:10 PM
To: Jones, William; Natanblut, Sharon; Smegal, Deborah; Wathen, John; Bigler, Jeff
Subject: FW: 4th FDA-EPA meeting on fish advice

Ex. 5 - Deliberative Process

From: Larimer, Lisa
Sent: Tuesday, May 12, 2015 1:06 PM
To: 'Jones, William'; Natanblut, Sharon; Bigler, Jeff; Smegal, Deborah; Wathen, John
Subject: RE: 4th FDA-EPA meeting on fish advice

Thanks, Bill. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Tuesday, May 12, 2015 11:15 AM
To: Larimer, Lisa; Natanblut, Sharon; Bigler, Jeff; Smegal, Deborah; Wathen, John
Subject: RE: 4th FDA-EPA meeting on fish advice

Ex. 5 - Deliberative Process

From: Jones, William
Sent: Tuesday, May 12, 2015 9:41 AM
To: 'Larimer, Lisa'; Natanblut, Sharon; Bigler, Jeff; Smegal, Deborah; Wathen, John
Subject: RE: 4th FDA-EPA meeting on fish advice

Agenda looks good, and I can still be your contact. We have a small cafeteria in our building, which works if you just want some kind of a sandwich. Some people get lunch there every day; I generally brownbag. Anything else is a 15 minute walk and not much better. I do recommend that we break at 11:50 for those who want to get something at the cafeteria…at noon or shortly thereafter you can be in line for 10 minutes sometimes.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, May 12, 2015 9:34 AM
To: Natanblut, Sharon; Jones, William; Bigler, Jeff; Smegal, Deborah; Elkin, Ted; Wathen, John
Subject: RE: 4th FDA-EPA meeting on fish advice

I believe the draft agenda I sent yesterday (let me know if it did not go out!) had 12-1 for lunch. It also had some questions for you FDA folks, such as is Bill the person we should contact at the front desk (I still have his numbers), and are there places to eat nearby or should we brownbag it?

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, May 11, 2015 7:52 PM
To: Jones, William; Larimer, Lisa; Bigler, Jeff; Smegal, Deborah; Elkin, Ted; Wathen, John
Subject: RE: 4th FDA-EPA meeting on fish advice

Thanks.

From: Jones, William
Sent: Monday, May 11, 2015 6:47 PM

To: Natanblut, Sharon; Larimer.Lisa@epa.gov; Bigler.Jeff@epa.gov; Smegal, Deborah; Elkin, Ted; Wathen.John@epa.gov
Subject: Re: 4th FDA-EPA meeting on fish advice

That sounds good to me.

From: Natanblut, Sharon
Sent: Monday, May 11, 2015 06:15 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Bigler, Jeff <Bigler.Jeff@epa.gov>; Jones, William; Smegal, Deborah; Elkin, Ted; Wathen, John <Wathen.John@epa.gov>
Subject: RE: 4th FDA-EPA meeting on fish advice

Hi there,

Turns out I have an HHS conference call between 12 and 12:30 on Wednesday. Would you mind if we scheduled that time for lunch?

Thanks.

Sharon

-----Original Appointment-----
From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, April 16, 2015 10:45 AM
To: Larimer, Lisa; Bigler, Jeff; Jones, William; Smegal, Deborah; Natanblut, Sharon; Elkin, Ted; Wathen, John
Subject: 4th FDA-EPA meeting on fish advice
When: Wednesday, May 13, 2015 9:00 AM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: CFSAN CP Room 2E-032

Main topic: Tackle the response to comments

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Jones, William
Sent: Tue 5/12/2015 3:15:13 PM
Subject: RE: 4th FDA-EPA meeting on fish advice

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Jones, William
Sent: Tuesday, May 12, 2015 9:41 AM
To: 'Larimer, Lisa'; Natanblut, Sharon; Bigler, Jeff; Smegal, Deborah; Wathen, John
Subject: RE: 4th FDA-EPA meeting on fish advice

Agenda looks good, and I can still be your contact. We have a small cafeteria in our building, which works if you just want some kind of a sandwich. Some people get lunch there every day; I generally brownbag. Anything else is a 15 minute walk and not much better. I do recommend that we break at 11:50 for those who want to get something at the cafeteria…at noon or shortly thereafter you can be in line for 10 minutes sometimes.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, May 12, 2015 9:34 AM
To: Natanblut, Sharon; Jones, William; Bigler, Jeff; Smegal, Deborah; Elkin, Ted; Wathen, John
Subject: RE: 4th FDA-EPA meeting on fish advice

I believe the draft agenda I sent yesterday (let me know if it did not go out!) had 12-1 for lunch. It also had some questions for you FDA folks, such as is Bill the person we should contact at the front desk (I still have his numbers), and are there places to eat nearby or should we brownbag it?

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, May 11, 2015 7:52 PM
To: Jones, William; Larimer, Lisa; Bigler, Jeff; Smegal, Deborah; Elkin, Ted; Wathen, John
Subject: RE: 4th FDA-EPA meeting on fish advice

Thanks.

From: Jones, William
Sent: Monday, May 11, 2015 6:47 PM
To: Natanblut, Sharon; Larimer.Lisa@epa.gov; Bigler.Jeff@epa.gov; Smegal, Deborah; Elkin, Ted; Wathen.John@epa.gov
Subject: Re: 4th FDA-EPA meeting on fish advice

That sounds good to me.

From: Natanblut, Sharon
Sent: Monday, May 11, 2015 06:15 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Bigler, Jeff <Bigler.Jeff@epa.gov>; Jones, William; Smegal, Deborah; Elkin, Ted; Wathen, John <Wathen.John@epa.gov>
Subject: RE: 4th FDA-EPA meeting on fish advice

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Thanks.

Sharon

-----Original Appointment-----
From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, April 16, 2015 10:45 AM
To: Larimer, Lisa; Bigler, Jeff; Jones, William; Smegal, Deborah; Natanblut, Sharon; Elkin, Ted; Wathen, John
Subject: 4th FDA-EPA meeting on fish advice
When: Wednesday, May 13, 2015 9:00 AM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: CFSAN CP Room 2E-032

Main topic: Tackle the response to comments

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Naidenko, Olga[Naidenko.Olga@epa.gov]
From: Jones, William
Sent: Mon 7/6/2015 4:20:32 PM
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

From: Smegal, Deborah
Sent: Monday, July 06, 2015 12:14 PM
To: Larimer, Lisa; Jones, William; Fontenelle, Samantha; Natanblut, Sharon; Bigler, Jeff; Wathen, John; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Sounds good to me…

Ex. 5 - Deliberative Process

debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Monday, July 06, 2015 12:06 PM
To: Jones, William; Fontenelle, Samantha; Natanblut, Sharon; Smegal, Deborah; Bigler, Jeff; Wathen, John; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Thursday, July 02, 2015 4:50 PM
To: Fontenelle, Samantha; Larimer, Lisa; Natanblut, Sharon; Smegal, Deborah; Bigler, Jeff; Wathen, John; Naidenko, Olga
Subject: Re: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

From: Fontenelle, Samantha [mailto:Fontenelle.Samantha@epa.gov]
Sent: Thursday, July 02, 2015 04:41 PM
To: Jones, William; Larimer, Lisa <Larimer.Lisa@epa.gov>; Natanblut, Sharon; Smegal, Deborah; Bigler, Jeff <Bigler.Jeff@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Naidenko, Olga <Naidenko.Olga@epa.gov>
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Thursday, July 02, 2015 3:16 PM
To: Larimer, Lisa; Natanblut, Sharon; Smegal, Deborah; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga

Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

One fairly minor edit.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, July 02, 2015 3:13 PM
To: Natanblut, Sharon; Jones, William; Smegal, Deborah; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Wednesday, July 01, 2015 6:15 PM
To: Larimer, Lisa; Jones, William; Smegal, Deborah; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga

Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, July 01, 2015 5:23 PM
To: Jones, William; Natanblut, Sharon; Smegal, Deborah; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Wednesday, July 01, 2015 5:22 PM
To: Natanblut, Sharon; Larimer, Lisa; Smegal, Deborah; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

It would be great if we could.

From: Natanblut, Sharon
Sent: Wednesday, July 01, 2015 4:54 PM
To: Larimer, Lisa; Smegal, Deborah; Jones, William; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, July 01, 2015 4:51 PM
To: Natanblut, Sharon; Smegal, Deborah; Jones, William; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Wednesday, July 01, 2015 4:40 PM
To: Smegal, Deborah; Larimer, Lisa; Jones, William; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Thanks Lisa. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Sharon

From: Smegal, Deborah
Sent: Wednesday, July 01, 2015 2:41 PM
To: Larimer, Lisa; Natanblut, Sharon; Jones, William; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Sounds good to me.

Thanks for taking the lead on this.

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, July 01, 2015 2:35 PM
To: Natanblut, Sharon; Smegal, Deborah; Jones, William; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Wednesday, July 01, 2015 9:22 AM
To: Smegal, Deborah; Jones, William; Larimer, Lisa; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: Re: Don't hate me, but this might be another good Q&A for the fish advice

That would be awesome!

Sent from my BlackBerry 10 smartphone.

From: Smegal, Deborah

Sent: Wednesday, July 1, 2015 9:10 AM

To: Jones, William; Natanblut, Sharon; Larimer.Lisa@epa.gov; Bigler.Jeff@epa.gov; Wathen.John@epa.gov; Fontenelle.Samantha@epa.gov; Naidenko.Olga@epa.gov

Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Hi,

Ex. 5 - Deliberative Process

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Jones, William
Sent: Monday, June 29, 2015 11:00 PM
To: Natanblut, Sharon; Larimer.Lisa@epa.gov; Smegal, Deborah; Bigler.Jeff@epa.gov; Wathen.John@epa.gov; Fontenelle.Samantha@epa.gov; Naidenko.Olga@epa.gov
Subject: Re: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

From: Natanblut, Sharon
Sent: Monday, June 29, 2015 05:19 PM
To: Jones, William; Larimer, Lisa <Larimer.Lisa@epa.gov>; Smegal, Deborah; Bigler, Jeff <Bigler.Jeff@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>; Naidenko, Olga <Naidenko.Olga@epa.gov>
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

From: Jones, William
Sent: Monday, June 29, 2015 5:01 PM
To: Larimer, Lisa; Natanblut, Sharon; Smegal, Deborah; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: RE: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Monday, June 29, 2015 4:53 PM
To: Natanblut, Sharon; Jones, William; Smegal, Deborah; Bigler, Jeff; Wathen, John; Fontenelle, Samantha; Naidenko, Olga
Subject: Don't hate me, but this might be another good Q&A for the fish advice

Ex. 5 - Deliberative Process

Lisa Larimer, P.E.

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Natanblut, Sharon
Sent: Thur 10/15/2015 10:08:48 PM
Subject: What do you think???
FISH_CHART_H_10.15.pdf

Sent from my BlackBerry 10 smartphone.

[redacted]

Here it is...

On Thu, Oct 15, 2015 at 5:38 PM, Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov> wrote:

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]
From: Smegal, Deborah
Sent: Thur 10/15/2015 8:37:54 PM
Subject: FW: revised fish advice documents
Fish Advice Qs and As-10 15 15.docx
Response to HHS comments 10.15.15.docx
technical web page-fish advice- 10.15.15 (3).docx
Summary Table of Response to Public comments 10.15.15.docx

Hi Lisa and John,

Here are the latest versions dated 10.15.15…..

Thanks for your input.

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Smegal, Deborah
Sent: Thursday, October 15, 2015 4:36 PM
To: Natanblut, Sharon; Jones, William
Cc: Boon, Caitlin; Trumbo, Paula; McKinnon, Robin; Bernard, Susan; Elkin, Ted; Steadman, Marquita B
Subject: revised fish advice documents

Hi,

Attached please find all the latest documents to include:

(1) Response to HHS comments in a table format

(2) Qs and As with track changes

(3) Technical document with track changes

(4) Response to Public comment document with track changes

This incorporates input from EPA, and Paula,

I named all the files with 10.15.15 for version control.

I think Marquita has the cover memo that will accompany the responses.

Thanks for all your comments and input.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Wathen, John[Wathen.John@epa.gov]; Lubin, Lisa[Lisa.Lubin@fda.hhs.gov]
Cc: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Steadman, Marquita B[Marquita.Steadman@fda.hhs.gov]
From: Natanblut, Sharon
Sent: Fri 1/13/2017 3:31:04 PM
Subject: RE: Fish Advice Qs and As 1-12-2017.for final small group review.docx
removed.txt

Thanks.

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Friday, January 13, 2017 10:04 AM
To: Natanblut, Sharon; Lubin, Lisa
Cc: Smegal, Deborah; Jones, William; Steadman, Marquita B
Subject: Re: Fish Advice Qs and As 1-12-2017.for final small group review.docx

Sharon-

Ex. 5 - Deliberative Process

~John

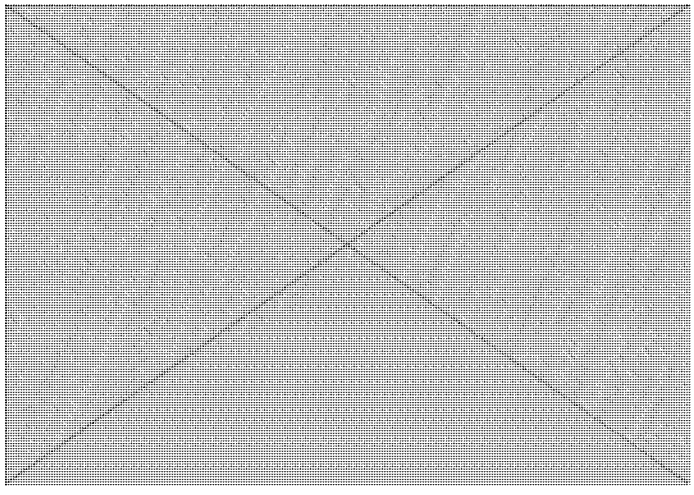
From: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Sent: Friday, January 13, 2017 9:04 AM
To: Lubin, Lisa; Wathen, John
Cc: Smegal, Deborah; Jones, William; Steadman, Marquita B
Subject: Fish Advice Qs and As 1-12-2017.for final small group review.docx

Hi guys,

Ex. 5 - Deliberative Process

Sharon

Ex. 5 - Deliberative Process



To: Lubin, Lisa[Lisa.Lubin@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Steadman, Marquita B[Marquita.Steadman@fda.hhs.gov]
From: Natanblut, Sharon
Sent: Fri 1/13/2017 2:04:23 PM
Subject: Fish Advice Qs and As 1-12-2017.for final small group review.docx
Fish Advice Qs and As 1-12-2017.for final small group review.docx

Hi guys,

Ex. 5 - Deliberative Process

Sharon

Ex. 5 - Deliberative Process

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Bigler, Jeff[Bigler.Jeff@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Spungen, Judith[Judith.Spungen@fda.hhs.gov]
From: Carrington, Clark D
Sent: Fri 4/10/2015 1:10:57 PM
Subject: RE: Ex. 5 - Deliberative Process fish advice

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, April 09, 2015 2:58 PM
To: Carrington, Clark D
Cc: Bigler, Jeff; Wathen, John
Subject: Data gaps for fish advice

Clark-

Since you're heading off for jolly ol' England soon, we'd really like to benefit from your expertise before you go. Ideally **we would like to** Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process **before the 4/14 meeting**, but definitely before you leave. I know it seems like a lot, but I think the priorities would be for #1 & #5.

1. Do you have species-specific mercury concentrations for:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Thanks,

Lisa

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Jones, William
Sent: Mon 5/2/2016 8:12:58 PM
Subject: RE: 2014 draft fish advice at COSTCO

Interesting.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Smegal, Deborah
Sent: Monday, May 02, 2016 2:57 PM
To: Jones, William; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Subject: 2014 draft fish advice at COSTCO

Hi,

I was shopping at Costco recently and noticed the 2014 draft advice was posted in about 4 areas of the frozen fish section of the store (right above the freezer). Thought you might find that interesting. I did not see it at the fresh fish section or near the canned tuna—but I was not looking that hard, so I could have missed it. I will look again next time I go.

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Larimer, Lisa
Location: 1-855-564-1700; DCRoomWest6210AA/DC-CCW-OST <DCRoomWest6210AA@epa.gov>
Importance: Normal
Subject: Fish advice strategy
Start Date/Time: Mon 5/11/2015 6:00:00 PM
End Date/Time: Mon 5/11/2015 7:00:00 PM

Call 1-855-564-1700
Conference code =
Participant code = Ex. 6 - Personal Privacy

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Bigler, Jeff[Bigler.Jeff@epa.gov]; Wathen, John[Wathen.John@epa.gov]; John Wathen Ex. 6 - Personal Privacy
From: Wathen, John
Sent: Fri 5/8/2015 7:41:53 PM
Subject: Combined answers
Comment Response Table-colorcodedjwll5-8.docx

Lisa-

I combined your substantial response effort with my sheet and answers I cranked on today. This is a good exercise and allows us to test the flavor of responses.

I note we never got to our prep meeting for next week. I could have some time Mon either early or late…

~John

John Wathen, Acting Chief

Fish, Shellfish, Beaches, & Outreach Branch (4305 T)

<'}}}>< _/)~~~ <'}}}>< _/)~~~ <'}}}><

Standards and Health Protection Division

Office of Science and Technology

Office of Water

US Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, DC 20460

202-566-0367 phone

202-566-0409 fax

http://www.epa.gov/waterscience

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Jones, William[William.Jones@fda.hhs.gov]; Wathen, John[Wathen.John@epa.gov]
From: Natanblut, Sharon
Sent: Tue 12/15/2015 10:15:38 PM
Subject: RE: FDA/EPA fish advice meeting

Never mind!

From: Natanblut, Sharon
Sent: Tuesday, December 15, 2015 5:05 PM
To: Smegal, Deborah; Larimer, Lisa; Jones, William; Wathen, John
Subject: RE: FDA/EPA fish advice meeting

Can someone please **Ex. 5 - Deliberative Process**
Thx.

-----Original Appointment-----
From: Smegal, Deborah
Sent: Thursday, December 10, 2015 10:51 AM
To: Smegal, Deborah; Larimer, Lisa; Natanblut, Sharon; Jones, William; Wathen, John
Subject: FDA/EPA fish advice meeting
When: Monday, December 14, 2015 2:00 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: CFSAN CP Room 2A023

I reserved a room near my office on the second floor. It is different than before but has a nice window.

Debbie

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, December 09, 2015 5:47 PM
To: Natanblut, Sharon; Jones, William; Smegal, Deborah
Cc: Wathen, John
Subject: Should we try to meet next Monday?

Ex. 5 - Deliberative Process, let's meet to figure out our next steps. It would be great if we could get together before John and I disappear for the holidays (starting Dec 18). John and I are free all of Monday afternoon and we're willing to travel out your way. Are you all available?

Lisa Larimer, P.E. | Team Leader
U.S. Environmental Protection Agency | Washington, DC
Office of Water | Standards and Health Protection Division
☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Bigler, Jeff
Sent: Wed 5/6/2015 2:25:23 PM
Subject: Re: Prep for 4th FDA-EPA meeting on fish advice

Ex. 5 - Deliberative Process

On May 5, 2015, at 2:48 PM, Wathen, John <Wathen.John@epa.gov> wrote:

Jeff-

My guess is you have the exposure factors handbook number on the tip of your tongue?

~John

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Tuesday, May 05, 2015 12:31 PM
To: Larimer, Lisa; Bigler, Jeff; Jones, William; Natanblut, Sharon; Elkin, Ted; Wathen, John; Naidenko, Olga; Fontenelle, Samantha
Subject: FW: Prep for 4th FDA-EPA meeting on fish advice

HI Everyone,

Ex. 5 - Deliberative Process

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Spungen, Judith
Sent: Tuesday, May 05, 2015 12:20 PM
To: Smegal, Deborah
Cc: Wirtz, Mark S
Subject: RE: Prep for 4th FDA-EPA meeting on fish advice

Hi Debbie,

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

-Judi

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Monday, May 04, 2015 2:58 PM
To: Bigler, Jeff; Jones, William; Smegal, Deborah; Natanblut, Sharon; Elkin, Ted; Wathen, John; Naidenko, Olga; Fontenelle, Samantha
Subject: Prep for 4th FDA-EPA meeting on fish advice

Hi everyone,

I thought I'd take a stab at getting us organized for our next meeting on May 13. Let's try to get as much of this done as we can before then.

Q&As

1. Does anyone have any more suggested edits to Q&As? Debbie sent some on 4/22.

Ex. 5 - Deliberative Process

Comment response

1. Our goal for the 5/13 meeting was to go through the responses to comments. In order to do that, I propose we **Ex. 5 - Deliberative Process** **Ex. 5 - Deliberative Process** I further propose that we **Ex. 5 - Deliberative Process** **Ex. 5 - Deliberative Process** In a later email I will send **Ex. 5 - Deliberative Process** **Ex. 5 - Deliberative Process**

Advice & chart

1. I have not had a chance to look closely at the draft chart that Sharon sent on 4/26, but if

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Thanks,

Lisa

Lisa Larimer, P.E.

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Ned Groth
Sent: Wed 11/5/2014 9:27:55 PM
Subject: My presentation from Monday
Groth critique.pptx

Dear John,

Great seeing you again and next time I will attach a name to the face!

Here is my Powerpoint from Monday, as you requested. I also submitted long written comments that make many of the same points with much greater detail. Let me know if you want that too.

Best regards,

Ned Groth
nedgroth@cs.com

A critique of the draft new FDA/EPA advice on seafood consumption and of FDA's communication about it

Presented by Edward Groth III, PhD.
Groth Consulting Services, Pelham, NY, USA

at the November 3, 2014 meeting of
the FDA's Risk Communication Advisory Committee
In Silver Spring, MD

The Communication Environment

American consumers are bombarded with advice about seafood consumption from diverse sources.

The main messages of the advice vary:

- Just eat more fish
  --focuses on benefits, often denies risks
- Eat fish, choose wisely
  --balances R/B but varies in emphasis and nuance
- Don't eat more fish
  --rare & usually based on sustainability, not health

Consumers are *confused*

- Perceptions of competing interests with different agendas, and of dueling experts, leave consumers uncertain about what or whom to believe.
- Most people are aware of the benefits and not very worried about the risks, ***but they don't know what to do***—i.e., which fish to eat or avoid.
- **Confused consumers are not likely to eat more fish, no matter how often they are told to.**
- One important step forward would be to align advice from various sources much more closely.

Two Major Opportunities

- Two ongoing federal initiatives offer opportunities to produce a template or model advice that most of the stakeholders could agree with and replicate—i.e., get most advice purveyors on the same page.
- The Dietary Guidelines for Americans are now being revised for a 2015 update;
- FDA and EPA are updating the 2004 fish consumption Advisory, today's topic.
- It seems essential that both efforts get it right, i.e., produce sound advice that promotes public health—and that they agree with each other.

Very different approaches

- DHHS has a Dietary Guidelines Advisory Committee, outside, independent experts, has spent more than a year reviewing scientific literature and drafting the basis for guidance on fish consumption (among other issues). Has held six public meetings. We won't know the results for another year or so.
- FDA/EPA formed a joint staff group, led by FDA, to update their advice. They have focused on analyzing the benefits and risks of fish consumption using a simulation model. A draft of proposed new advice was published in June for public comment. This is the first opportunity for public input since 2009.

Science-policy interactions (ideally) in food safety risk analysis

- First, scientists conduct an evidence-based assessment of risks and benefits.
- The assessment is communicated to policymakers, with an explicit statement of uncertainties, data gaps and limitations of the risk assessment.
- What is known and what is not known are weighed by policymakers, and value judgments (such as how much risk is acceptable, and how much precaution is needed to account for uncertainties) are applied.
- All of this is clearly communicated to the public.

Flaws in the FDA/EPA Process

- No (formal) external scientific input—B/R assessment done in house (by one scientist, one lawyer).
- B/R assessment focused entirely on modeling—as far as I can tell, not based at all on recent literature. Far too narrow and shaky as a basis for policy.
- Policy (the draft advice) seems largely developed by the same staff who did the risk/benefit assessment (who might be biased to overlook flaws in their own approach?) On principle, not a sound approach.
- The product—the draft advice—is seriously flawed.

The Draft Advice is WRONG

- **It has no sound basis in science.**
- **It does not acknowledge or take into account any uncertainties and limitations** in the benefit/risk assessment on which it is apparently based.
- **It does not accurately or helpfully guide women to choose low-mercury fish.** It actually recommends a 20- to 30-fold *increase* of consumption of the two largest current sources of methylmercury exposure.
- It is so one-sided that consumers seeking balanced advice will reject it as not credible nor trustworthy.

No Sound Basis In Science

This is a very serious criticism and I do not make it lightly. I have submitted a detailed written critique. In brief:

(1) The risk/benefit conclusions supporting the draft advice appear to be only those from the FDA's model. Models are useful for comparing options, but "All models are wrong," i.e., limited by the data and assumptions fed into them.

(2) My written comments identify multiple important scientific weaknesses, uncertainties and limitations of the FDA model. This effort, while admirable, ***cannot provide a credible or valid basis for policy*** (dietary advice).

(3) The advice is not linked in any discernible way to the extensive available empirical evidence from more than 20 recent epidemiological studies.

Evidence Not Considered

At least 20 epidemiological studies done since 2004, reviewed in my written comments, have, collectively:

--Repeatedly shown adverse effects of mercury exposure at levels of fish intake and mercury doses that occur in 5 to 15 percent of American women (per FDA's model);

--Reduced the LOAEL from 60 µg/day (in 2004) to about 2-3 µg/day in 2014—a 20-fold reduction in the minimum dose associated with measurable harm;

--Expanded the list of adverse effects associated with low-level mercury exposure to include fine motor coordination effects and ADHD, among others.

Implications:

- This empirical evidence **suggests that FDA's benefit-risk model is almost certainly wrong—in that it understates risks by a wide margin.**
- The most critical element of recent evidence is that the LOAEL today is **20-fold lower** than it was in 2004.
- But the draft advice recommends **almost exactly the same seafood choices—and so tolerates the same level of methylmercury exposure**—as in 2004.
- The consequences of following this advice would not be acceptable for public health.

Uncertainties

- As noted, there are many important uncertainties and limitations in the FDA's B/R assessment.
- There is no recognition of uncertainty in the draft advice. In presenting the advice to the media, FDA was questioned about critical uncertainties and denied, emphatically, that any relevant uncertainty exists—a fundamentally unscientific statement.
- One standard way to address uncertainty is to err on the side of caution, in case benefit/risk estimates are wrong. That standard strategy has not apparently been considered in drafting this advice.

The advice is not helpful

- The basic goals of the advice are to get women to eat more fish, and to get them to choose lower-mercury fish in order to minimize exposure and risk.
- **Those are the correct goals.**
- But the devil is in the details—for instance, which fish are called "low mercury," and recommended?
- In its recommended choices, the draft advice is simply and seriously **wrong** in several obvious ways, and **less than useful** in other ways.

What *could* advice achieve?

Fish consumption and estimated mercury exposure of an average woman in Norway and the United States:

	Fish Intake, grams/week	Mercury dose, µg/week	Average mercury in fish, ppm
Norway[1]	**392 g**	**11.3 µg**	0.029 ppm
United States[2]	**104 g**	**9.8 µg**	0.094 ppm

1 - Source of data, Haugen (2014)

2 - Source of Data, FDA benefit-risk assessment report (2014)

- Norwegian women eat almost four times as much fish per week, on average, as American women do.
- But weekly intake of mercury is almost the same in both countries, because the fish eaten in the US on average have far higher mercury levels.
- It is possible for American women to greatly increase fish consumption, and simultaneously to reduce their methylmercury exposure, if US women's seafood preferences (guided by advice) evolved over time to be more like Norwegian women's, i.e., to include mostly fish with much lower mercury content.

(*Norway is just an example—many similar countries*)

How that could happen:

To grasp this opportunity, help confused consumers choose wisely, and optimally improve public health, therefore, fish consumption advice should:

- Promote **increased** consumption of choices that are comparatively high in beneficial omega-3s and also low in methylmercury;
- Promote **decreased** consumption of higher-mercury fish, especially popular varieties that make significant contributions to women's overall mercury exposure.

Fish choices *really* matter

- Seafood items vary by over 145-fold in mercury level, and by at least 67-fold in omega-3 content.
- The omega-3/Hg ratio (i.e., benefit/risk ratio) of items in FDA's database varies by 1,360-fold.
- Doubling seafood intake without changing the mix of items chosen will double both benefits and risks.
- But changing which fish are eaten can change the benefit/risk ratio by more than 1,000 fold.
- Advice on WHICH fish to eat thus drives health outcomes much more powerfully than advice on HOW MUCH fish to eat, and is by far the most critical part of the advice.

Choices high in omega-3s and low in Hg

	DHA + EPA mg/4 oz	Market %
Herring, Anchovies & Shad	2300	1.55
Mackerel, Chub	1425	0.09
Mackerel, Atlantic & Atka	1370	0.57
Sardines	1360	0.64
Salmon, all types	1345	9.14
Trout, freshwater	1060	0.74
Tilefish, Atlantic	1040	<0.01
Whitefish	1040	0.16
Smelt	1015	0.05
Mussels & Oysters	800	0.59

Data source: Draft advice

Top 10 sources of mercury

Seafood Item	% Hg	Cum %
1. Canned Albacore Tuna	19.62	19.62
2. Canned Light Tuna	17.63	37.25
3. Fresh/Frozen Tuna	7.81	45.07
4. Cod	6.00	51.07
5. Pollock	5.76	56.83
6. Swordfish	5.75	62.58
7. Flatfish	3.44	66.02
8. Shrimp	3.13	69.15
9. Salmon	2.84	71.99
10. Orange Roughy	2.66	74.65

Data source: Groth, 2014

The advice recommends:

- Do not eat swordfish, shark, king mackerel, Gulf tilefish;
- Eat up to 6 oz/week of canned albacore tuna;
- Eat up to 12 oz/week of a variety of lower-mercury seafood;
- "Commonly eaten lower-mercury" choices include: salmon, shrimp, pollock, canned light tuna, tilapia, catfish and cod. (Tilapia & cod added since 2004)
- Other seafood choices (**40 of 52 market varieties**) are listed in a table but not mentioned in the advice.

In other words:

- Only one item on the Do Not Eat list (swordfish) is among the top 10 sources of mercury exposure.
- The Recommended list includes only one choice (salmon) high in omega-3s; most of the rest are low (not even medium) in omega-3s;
- FDA's stated basis for its recommended choices is that they are among the top ten in market share.
- The advice recommends increased consumption of three of the top four mercury exposure sources (canned albacore tuna, canned light tuna, cod).
- No advice is offered on the vast majority of choices.

"Lower-mercury fish"

- A central problem with the advice is that FDA has neither clearly nor correctly defined this term.
- Its list of "lower-mercury choices" is based on market share, not on a risk-based definition of mercury level.
- The average mercury level in US seafood is 0.072 ppm (FDA's own estimate, in its benefit/risk report).
- Two of the advice's "lower-mercury" choices (canned light tuna and cod) have well above-average Hg levels.
- About 25 fish and shellfish have ≤0.07 ppm mercury, but the draft advice ignores all of them that are not in the top-10 selling items.

Advice re canned tuna

Current US per capita consumption is 0.2 oz/week of canned albacore tuna and 0.6 oz/week of canned light tuna.

If pregnant women follow the draft FDA/EPA advice:

- 6 oz/week of **canned albacore tuna** represents a 30-fold increase in intake of the #1 US dietary mercury source;
- 12 oz/week of **canned light tuna** represents a 20-fold increase in intake of the #2 US dietary mercury source;
- The combined impact of these changes would increase women's total mercury dose by almost 10-fold;
- The claim that benefits of increased tuna consumption will outweigh this increase in risk is refuted by epidemiological evidence cited above and is ***simply not***

The Bottom Line:

- The draft advice, if followed, will greatly increase mercury exposure and risk among pregnant women, without significantly boosting omega-3 intake;
- The net effects of those dietary changes would be adverse, not beneficial, for public health;
- Many of us in the public-interest sector who have worked for years to improve fish consumption advice now feel we must make a concerted effort to get this draft revised into acceptable form.
- This is ***not*** advice all stakeholders can line up behind; so it represents a major lost opportunity.

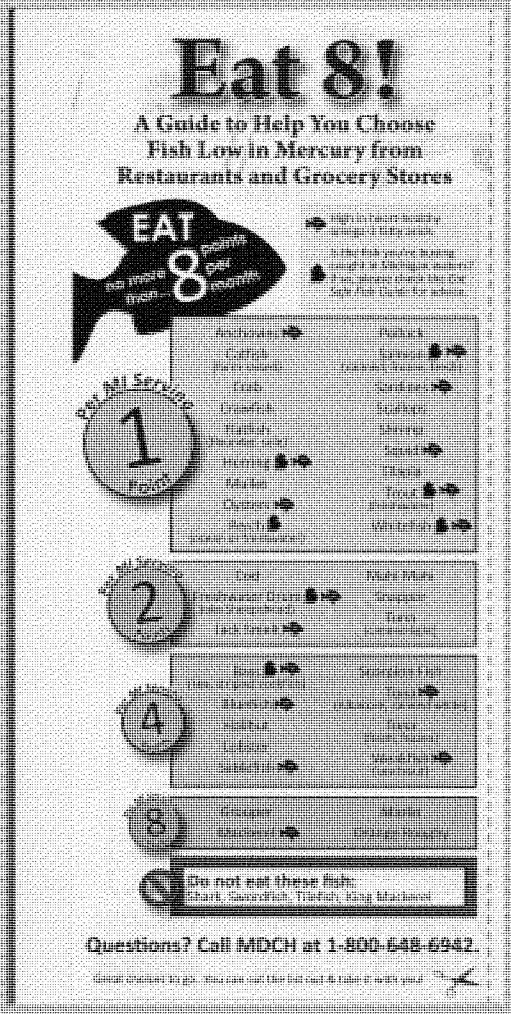
Presentation issues

- Substance aside, the draft advice is not presented in a useful, comprehensible format.
- Poor presentation will limit its effectiveness.
- The biggest problem is that the only information (just data, not advice) about 40 of 52 main seafood choices is in a hard-to-interpret appendix table.
- Virtually all examples of *useful* seafood advice sort choices into easily understood categories like "best choices," "avoid these," "also acceptable," etc.
- It seems imperative that the revised advice **include a chart that sorts all seafood choices** in that manner.

Some presentation tips:

- Many examples of well-designed charts exist—they are used by state health departments, NGOs and others.
- Charts can convey complex information in simple ways: How much fish to eat, which fish to eat (and not eat), which are high in omega-3s, which are high/low in mercury, which are sustainably caught.
- Good charts use non-verbal communication tools, like color-coding, placement (e.g., top to bottom), icons and point systems to flag choices, etc.
- There is no one best chart design—but a good chart of some kind is indispensable.

Examples of useful charts



Eat 8!

A Guide to Help You Choose Fish Low in Mercury from Restaurants and Grocery Stores

EAT 8 meals per month

Do not eat these fish: Shark, Swordfish, Tilefish, King Mackerel

Questions? Call MDCH at 1-800-648-6942.

Table 1

Eat More of These		Eat Less of These	
✔	Sardines ♥	▟	Tuna Steak
✔	Salmon (wild) ♥	▟	Salmon (farm-raised)
✔	Flounder ♥	▟	White Tuna (canned)
✔	Atlantic Mackerel ♥	▟	Halibut
✔	Pollock ♥	■	Catfish (farm-raised)
✔	Sole ♥		**Eat None of These**
✔	Cod	X	Tilefish
✔	Tilapia	X	Swordfish
✔	Haddock	X	Shark
✔	Light Tuna (canned)	X	King Mackerel
✔	Shellfish (oysters, shrimp, clams, scallops, lobster)	X	Striped Bass
		X	Bluefish

♥ Species especially low in contaminants and can be eaten more than twice a week

Chart 2. BEST AND WORST CHOICES, RANKED BY OMEGA-3:Hg RATIO

Best Choices (Ratio >200)	Ratio	Good Choices (Ratio 50-200)	Ratio	Fair Choices (Ratio 30-50)	Ratio	Poor Choices (Ratio 15-30)	Ratio	Worst Choices (Ratio <10)	Ratio
Suggested servings: WCBA&YC: 3 +/week Others: Same		**Suggested servings: WCBA&YC: 1/week Others: 2/week**		**Suggested servings: WCBA&YC: 0-2/month Others: 1/week**		**Suggested servings: WCBA&YC: 0-1/month Others: 2/month**		**Suggested servings: WCBA&YC: Do Not Eat Others: Eat rarely**	
Sardines	680	Mackerel, Chub	143	Sablefish	49	Fresh Tuna	17	Orange Roughy	0.5
Salmon	673	Smelt	127	Spiny Lobster	42	American Lobster	18	King Mackerel	5
Anchovies	460	Catfish	125	Flounder	38	Cod	18	Grouper	5
Mussels	400	Pollock	120	Plaice	38	Canned Light Tuna	22	Gulf Tilefish	6
Oysters	400	Butterfish	119	Sea Bass	38	Hake	23	Shark	7
Shrimp	400	Clams	115	Sole	38	Haddock	23	Swordfish	9
Shad	383	Tilapia	120	Spanish Mackerel	34	Monkfsh	23	Ling Cod	9
Herring	383	Whitefish	95			Canned Albacore Tuna	23	Scorpionfish	9
FW Trout	353	Atlantic Tilefish	80			Sea Trout	24	Marlin	10
Mackerel, Atlantic	228	Squid	78			Atlantic Croaker	26	Pacific Croaker	10
Mackerel, Atka	228	Crabs	62			Bluefish	28		
Scallops	220	Crayfish	60						

KEY Abbreviations: WCBA = Women of childbearing age; YC = Young children

Color-Coding:

- High in omega-3s and low in mercury; eat as often as you like
- Relatively low in mercury and moderate in omega-3s; good choices once a week
- Too low in omega-3s or high in mercury to eat often; eat occasionally
- Quite low in omega-3s or high in mercury or both; eat rarely
- High or very high in mercury and low in omega-3s; pregnant women SHOULD NOT EAT

Risk communication aspects

In presenting the advice to the media on June 10, FDA made many mistakes that novice risk communicators often make:

- They chose a non-expert spokesperson, whose answers to questions revealed basic ignorance of the issues;
- Numerous statements in both the advice and remarks to the media are either objectively untrue, partly true but so one-sided as to be very misleading, or claims to know something science cannot possibly know.
- These are all "cardinal sins" of risk communication that tend to make consumers reject the message.

Some final thoughts

- FDA's inept risk communication may lead consumers to distrust the agency and reject the advice;
- Given that the advice, in its current form, is likely to substantially harm public health, such disbelief and rejection might not be a bad thing;
- But it is simply *not acceptable* for the nation's chief food safety agency to issue such flawed advice on such an important topic. Therefore,
- The flaws in the advice must be corrected; and
- FDA has to learn how to communicate about it more honestly and effectively.

My Recommendations

- FDA ***must*** obtain independent expert advice on how to interpret and use epidemiological evidence.
- Make critical changes in the advice:

--Base it on empirical evidence, not modeling;

--Explicitly address uncertainty and precaution;

--Sort choices by both mercury and omega-3s;

--Define "low-mercury" as ≤0.06 ppm (7 µg/4 ounces);

--Limit items with mercury content between 0.06 and 0.13 ppm to one 4-ounce serving per week;

--Add canned albacore tuna and all items with >0.20 ppm Hg to the "do not eat" list for pregnant women;

--Include a fish choice chart sorting all 52 varieties.

As for its risk communication:

FDA needs to learn how to communicate more honestly with the public about risks, benefits and what is known and not known scientifically.

I hope this committee can help them do that.

I hope the committee will advise FDA, clearly and firmly, that if they hope to persuade consumers to eat more fish, and to maximize the excess of benefits over risks from seafood consumption, they cannot succeed unless they approach advice in a manner suggested in my comments here today.

Thank you for your attention.

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Smegal, Deborah
Sent: Wed 4/22/2015 10:25:02 PM
Subject: RE: Draft of fish advice after 3rd FDA-EPA meeting (4/22/15)
draft Qs and A's 4.22.15.docx

Hi,

Here is the latest draft of the Q's and A's. I added a few suggested edits to the EPA responses, but Sharon and Bill also need to weigh in.

I would prefer we hold the next meeting at FDA and would be happy to reserve a room.

Regards,

Debbie

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, April 22, 2015 2:38 PM
To: Natanblut, Sharon; Jones, William; Smegal, Deborah; Bigler, Jeff; Wathen, John
Subject: Draft of fish advice after 3rd FDA-EPA meeting (4/22/15)

Hi everyone,

Here is the version of the fish advice we developed this morning, and the final agenda in case anyone needs it for official records.

Lisa Larimer, P.E.

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 12/6/2016 8:14:12 PM
Subject: RE: changes made to fish advice chart and Q&A in response to HHS comments

The email said:

Ex. 5 - Deliberative Process

From: Wathen, John
Sent: Tuesday, December 06, 2016 3:05 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: changes made to fish advice chart and Q&A in response to HHS comments

Ex. 5 - Deliberative Process

~John

From: Larimer, Lisa
Sent: Tuesday, December 06, 2016 3:04 PM
To: Wathen, John <Wathen.John@epa.gov>
Subject: RE: changes made to fish advice chart and Q&A in response to HHS comments

What did you think was happening?

From: Larimer, Lisa
Sent: Tuesday, December 06, 2016 3:02 PM

To: Wathen, John <Wathen.John@epa.gov>
Subject: RE: changes made to fish advice chart and Q&A in response to HHS comments

Ex. 5 - Deliberative Process

From: Wathen, John
Sent: Tuesday, December 06, 2016 3:01 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: changes made to fish advice chart and Q&A in response to HHS comments

Ex. 5 - Deliberative Process

~John

From: Larimer, Lisa
Sent: Tuesday, December 06, 2016 2:50 PM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Cc: Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Subject: FYI: changes made to fish advice chart and Q&A in response to HHS comments

Track changes version of Q&A attached.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Will let you know as soon as I hear from FDA on next steps.

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Tuesday, December 06, 2016 10:24 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>
Cc: Wathen, John <Wathen.John@epa.gov>
Subject: RE: We have translations!

Hi,

Ex. 5 - Deliberative Process

Latest Q and A's with track changes is attached.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Monday, December 05, 2016 10:51 PM
To: Natanblut, Sharon; Smegal, Deborah; Jones, William
Cc: Wathen, John
Subject: We have translations!

We have the chart text and Q&A translated into Spanish Ex. 5 - Deliberative Process Other languages forthcoming. Let me know what changes are made to the chart and Q&A so I can make sure the translations are changed too. . .

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Tue 12/6/2016 8:02:30 PM
Subject: RE: changes made to fish advice chart and Q&A in response to HHS comments

Right, we are **Ex. 5 - Deliberative Process**

From: Wathen, John
Sent: Tuesday, December 06, 2016 3:01 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: changes made to fish advice chart and Q&A in response to HHS comments

I thought we Ex. 5 - Deliberative Process

~John

From: Larimer, Lisa
Sent: Tuesday, December 06, 2016 2:50 PM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Cc: Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Subject: FYI: changes made to fish advice chart and Q&A in response to HHS comments

Track changes version of Q&A attached.

Uncorrected chart is attached: changes to be made to chart include:

Ex. 5 - Deliberative Process

(2) Switch the EPA logo to the one that says Environmental Protection Agency on the side to

more closely mirror the logo FDA is using.

Will let you know as soon as I hear from FDA on next steps.

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Tuesday, December 06, 2016 10:24 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>
Cc: Wathen, John <Wathen.John@epa.gov>
Subject: RE: We have translations!

Hi,

The chart changes: **Ex. 5 - Deliberative Process**

Latest Q and A's with track changes is attached.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

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Cc: Wathen, John
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Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Smegal, Deborah
Sent: Wed 4/22/2015 1:07:16 PM
Subject: RE: 3rd FDA-EPA meeting on fish advice: proposed agenda & EPA edits to Q&As
team comments methyl Mercury Qs and As_4.21.15.doc

Hi,

Here are the suggested responses to the Q's and A's that FDA was assigned for discussion today.

Regards,

Debbie

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, April 21, 2015 2:15 PM
To: Natanblut, Sharon; Jones, William; Smegal, Deborah; Bigler, Jeff; Wathen, John
Subject: 3rd FDA-EPA meeting on fish advice: proposed agenda & EPA edits to Q&As

Hi everyone,

Here is a proposed agenda and a copy of our full set of edits to the Q&As so you can see it before the meeting if you have time. If you have yours ready to share, we'd appreciate seeing them too.

Question about logistics: Does someone need to meet us at the door? I'm assuming we're meeting in the building at the corner of River Road and Paint Brush Parkway; please let me know if I'm incorrect. (I've never been there.) Can you provide the phone number of a contact person in case one of us is running late?

Proposed agenda

8:30-8:45 Review of agenda

8:45-9:00 Review of draft advice

9:00-9:30 Draft mock-ups of advice

9:30 – 10:00 Draft mock-ups of fish chart

10:00 – 10:15 Break

10:45 – 12:15 Revisions to Q&As

12:15-12:30 Next steps

See you tomorrow!

Lisa Larimer, P.E.

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Wathen, John[Wathen.John@epa.gov]
From: Wathen, John
Sent: Thur 4/16/2015 8:03:20 PM
Subject: FW: Second FDA-EPA Meeting on Fish Advice
Agenda-Fish Advice-041415 FDA-EPA mtg.docx
Handout 2 Fish advice chart-041315.xlsx
Handout 5 Annotated QA-040715.docx
Handout 6 Table of Synthesized Comments-040715.docx
Handout 1 Summary of All Public Comments on Advice-040715.docx

---

From: Larimer, Lisa
Sent: Monday, April 13, 2015 1:05 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: RE: Second FDA-EPA Meeting on Fish Advice

Hi everyone. Here is the agenda and handouts 1, 2, 5 and 6 for tomorrow's meeting.
[Sharon, if you bring or send the electronic file with the projected mark-ups to the advice, I can project it on the big screen.]

Logistics:
Enter through the EPA West entrance at 1301 Constitution Ave, NW (same one as before) - Federal Triangle metro stop.
Call John Wathen at 202-566-0367 to lead you up.
Meeting will be in 6105A.
Call-in number is 855-564-1700; conference extension = **Ex. 6 - Personal Privacy**

We look forward to seeing you! We have a jam-packed agenda.

Lisa Larimer, P.E.
U.S. Environmental Protection Agency | Washington, DC
Office of Water | Standards and Health Protection Division
☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

-----Original Appointment-----
From: Robiou, Grace
Sent: Tuesday, March 17, 2015 3:31 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Larimer, Lisa; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: Second FDA-EPA Meeting on Fish Advice
When: Tuesday, April 14, 2015 9:00 AM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest6105AAssateague/DC-EPA-West-OST

From: Larimer, Lisa
Location: FDA (College Park), Room 2E-032 in the CFSAN Wiley building
Importance: Normal
Subject: 3rd FDA-EPA meeting on fish advice
Start Date/Time: Wed 4/22/2015 12:30:00 PM
End Date/Time: Wed 4/22/2015 4:30:00 PM

To: Wathen, John[Wathen.John@epa.gov]
From: Barash, Shari
Sent: Wed 12/9/2015 1:28:00 PM
Subject: FW: 2 documents on fish advice
Ex. 5 - Deliberative Process
Options for fish advice 12-8-15.docx

FYI

Shari Z. Barash

Acting Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Southerland, Elizabeth
Sent: Tuesday, December 08, 2015 4:04 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Cc: Bethel, Heidi <Bethel.Heidi@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: 2 documents on fish advice

Ex. 5 - Deliberative Process

To: Wathen, John[Wathen.John@epa.gov]
From: Barash, Shari
Sent: Wed 12/9/2015 1:25:18 PM
Subject: FW: 2 documents on fish advice

Shari Z. Barash

Acting Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Southerland, Elizabeth
Sent: Wednesday, December 09, 2015 7:08 AM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Cc: Bethel, Heidi <Bethel.Heidi@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Re: 2 documents on fish advice

Will do.

Sent from my iPhone

On Dec 8, 2015, at 10:26 PM, Beauvais, Joel <Beauvais.Joel@epa.gov> wrote:

Ex. 5 - Deliberative Process

From: Southerland, Elizabeth
Sent: Tuesday, December 8, 2015 4:03 PM
To: Beauvais, Joel
Cc: Bethel, Heidi; Hisel-Mccoy, Sara; Barash, Shari; Larimer, Lisa
Subject: 2 documents on fish advice

Ex. 5 - Deliberative Process

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Li, Cissy[Cissy.Li@fda.hhs.gov]
From: Jones, William
Sent: Fri 11/4/2016 6:36:51 PM
Subject: RE: Comparing other fish advice

Nicely done!

-----Original Message-----
From: Smegal, Deborah
Sent: Friday, November 04, 2016 2:35 PM
To: Jones, William; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Cc: Li, Cissy
Subject: FW: Comparing other fish advice

Hi,

Ex. 5 - Deliberative Process

Debbie

-----Original Message-----
From: Li, Cissy
Sent: Wednesday, November 02, 2016 2:07 PM
To: Smegal, Deborah
Subject: Comparing other fish advice

Hi Debbie,

Ex. 5 - Deliberative Process

Let me know if you want any additional information to be included.

Cissy

Cissy Li, PhD
ORISE Fellow
Contaminant Assessment Branch
Division of Risk and Decision Analysis
Office of Analytics and Outreach, CFSAN, FDA Room 2A-031
240-402-2857

To: Wathen, John[Wathen.John@epa.gov]
Cc: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Christensen, Christina
Sent: Tue 11/1/2016 8:05:59 PM
Subject: RE: Discuss fish advice communications needs

Just updated the calendar invite with a call in number.

From: Wathen, John
Sent: Tuesday, November 01, 2016 4:04 PM
To: Christensen, Christina <Christensen.Christina@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Discuss fish advice communications needs

Christina-

I am teleworking tomorrow AM, but if you'll open up a line, I'll call in.

~John

-----Original Appointment-----
From: Christensen, Christina
Sent: Tuesday, November 01, 2016 3:57 PM
To: Larimer, Lisa; Barash, Shari; Fontenelle, Samantha; Wathen, John; Lalley, Cara; Gerstein, Arielle
Subject: Discuss fish advice communications needs
When: Wednesday, November 02, 2016 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest6105ERockCreek/DC-EPA-West-OST

Setting up time to discuss communications needs for EPA/FDA fish advice.

From: Christensen, Christina
Location: DCRoomWest6105ERockCreek/DC-EPA-West-OST
Importance: Normal
Subject: Discuss fish advice communications needs
Start Date/Time: Wed 11/2/2016 2:00:00 PM
End Date/Time: Wed 11/2/2016 3:00:00 PM

ADDING CALL IN NUMBER

Ex. 6 - Personal Privacy

Setting up time to discuss communications needs for EPA/FDA fish advice.

To: Hawkins, Denise[Hawkins.Denise@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Southerland, Elizabeth
Sent: Mon 10/27/2014 2:34:42 PM
Subject: Fwd: seafood advice layout
Fish_What_Pregnant_2.pdf
ATT00001.htm
Fish_What_Pregnant_3.pdf
ATT00002.htm

Sent from my iPhone

Begin forwarded message:

From: "Natanblut, Sharon" <Sharon.Natanblut@fda.hhs.gov>
To: "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Subject: FW: seafood advice layout

Hi Betsy,

Ex. 5 - Deliberative Process

Many thanks.
Sharon

To: Wathen, John[Wathen.John@epa.gov]
From: Dick Wathen
Sent: Wed 8/24/2016 7:33:59 AM
Subject: Re: FYI: New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

Good! We'll keep in touch.

W

From: Wathen, John <Wathen.John@epa.gov>
Sent: Tuesday, August 23, 2016 7:09 PM
To: Dick Wathen
Subject: RE: FYI: New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

I get plenty of exercise, brother. Never miss a day.

~J

From: Dick Wathen [mailto: **Ex. 6 - Personal Privacy**
Sent: Tuesday, August 23, 2016 2:00 PM
To: Wathen, John <Wathen.John@epa.gov>
Subject: Re: FYI: New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

Don't forget to get some exercise.

Love

Bro

From: Wathen, John <Wathen.John@epa.gov>
Sent: Tuesday, August 23, 2016 12:09 PM
To: Axie N.; Frederick Sheehan; Diane Wathen; Ex. 6 - Personal Privacy Dick Wathen
Cc: John Wathen
Subject: FW: FYI: New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

Big one I am working on.

~J

From: Conerly, Octavia
Sent: Tuesday, August 23, 2016 8:00 AM
To: OST-EVERYONE <OSTEVERYONE@epa.gov>
Subject: FYI: New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

FYI…

New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

August 22, 2016

The Food and Drug Administration (FDA) has initiated another peer review related to the joint advisory that EPA and FDA released in 2014 recommending amounts of fish that pregnant women and those who may be pregnant should eat, though a former FDA source says that it is unlikely the long-stalled update will be completed before year's end.

The agencies released a draft update to their joint advisory two years ago, following much prodding from various senators and stakeholders. But the document, which was widely panned by environmentalists concerned that it encouraged women to eat more fish without providing adequate information

about how to avoid methyl mercury, has yet to be finalized.

Now, FDA is undertaking another peer review of "[t]echnical information on development of fish consumption advice," according to an undated peer review plan posted on FDA's website. The document does not explain exactly what is being peer-reviewed, describing the subject of the review as the "technical information and methodology to support the scientific basis for the fish consumption recommendations," and its purpose as evaluating "methods, data and assumptions." *Relevant documents are available on InsideEPA.com. (Doc. ID: 193972)*

An FDA spokeswoman describes the effort as "a peer review of the appropriateness of the data we are considering employing, the assumptions we are considering making, and the calculations that we are considering using, in developing our updated fish consumption advice."

The spokeswoman does not specify what type of data is under review. The last draft advisory underwent a peer review by FDA's risk communication federal advisory committee last year, but this new review could address some data about levels of mercury and beneficial oils and fatty acids in various fish species, or a controversial quantitative risk-benefit model for fish consumption that FDA quietly finalized in 2014 along with release of the draft advice, among other topics.

The peer review will be of the lowest level of scrutiny, according to the plan, which says it was to be conducted in July. The spokeswoman says that the "peer review will likely be completed this fall, and the results will impact the time frame for completing the final fish consumption advice."

A former FDA source predicts that the advisory will not be finalized until after a new administration is in place, and news of the peer review did not change that impression. "Conducting another peer review of something that is ill defined is a delaying tactic which is par for the course," the source says.

Further delaying finalizing updated advice have been retirements of multiple scientists, managers and staff at both agencies long involved in the fish advisory discussions, as waiting for the new FDA commissioner, Robert Califf, to become familiar with the issue after being confirmed last February. The source adds that disagreement over the advisory's content has further delayed finalizing the advisory.

EPA last year proposed changes to the 2014 draft, including listing certain species as "do not eat" and others as "eat no more than once per week, but FDA did not list the proposal, the source says. "The gist of what the FDA people were saying [in response] was the proposed changes were completely inconsistent with the [FDA] net benefits [model] . . . there is no basis for the groupings," the source says.

The advisory aims to inform consumers, particularly pregnant women, on what fish to eat and which to avoid to balance the benefits of eating fish, a lean protein containing omega 3 and other beneficial oils that contribute to healthy eye and brain development and protect cardiovascular health, with the risk that fish can contain methyl mercury, a potent neurotoxin. The agencies' earlier fish advisories appear to have led to dramatic reductions in the amount of fish that American women eat, raising concerns that they are missing the many benefits that fish consumption brings.

Crafting good advice is further complicated because different fish species vary in both mercury levels and levels of beneficial oils. In recent years, some public health experts have sought to use models to better understand the complexity of the risk-benefit scenarios for different fish species.

But FDA's model, released in final form along with the draft advice update, has been highly controversial since a first draft was released for peer review and public comment in 2008. Comments from EPA's National Center for Environmental Assessment were particularly harsh.

The 2014 draft advice recommends that American women eat 8 to 12 ounces of fish per week, and highlights a handful of species to avoid eating because of their high mercury content. But both environmentalists and fishing industry representatives have protested the draft, with environmentalists arguing that the advice opens women up to greater possibility of mercury exposure. Fishing industry representatives, meanwhile, argue that FDA's model, which underlies the advice, shows that it is safe to eat more fish, including particular species like tuna, and that the advice should encourage women to eat more fish.

FDA's model, however, continues to undergo scrutiny. Last year, scientists at state agencies in Connecticut and Minnesota published their own model, which indicated a greater mercury risk than FDA's model, particularly for certain higher mercury species like tuna and swordfish.

Now, Edward Groth III, a former Consumers Union scientist and consultant, has published a new critique of fish consumption risk-benefit models, comparing results from various models with epidemiology studies over recent decades to

evaluate the models and try to improve their performance. "Simply put, it is not a sound policy approach to choose to believe a model and ignore the epidemiological evidence, as the U.S. FDA and EPA have recently proposed to do," Groth concludes in the paper published in *Environmental Research* in August, citing the agencies' draft 2014 advisory. "Disparities between models and epidemiology need to be resolved, so that both types of evidence can be integrated to provide more comprehensive, coherent and scientifically defensible advice."

Groth proposes "align[ing] FDA's model results with recent epidemiological evidence." Groth's analysis results in serving size recommendations for 60 different fish species, which consider both mercury and Omega 3 polyunsaturated fatty acids. "The final serving sizes take advantage of the model's discriminatory ability but are also consistent with recent epidemiology-based risk and benefit estimates," Groth writes.

Groth argues that by contrast, the agencies' draft advice, which recommends that women eat 8-12 ounces per week of lower mercury fish, but then identifies only four high mercury species to avoid, "offers little practical guidance for consumers and is unlikely to change either fish consumption patterns or [mercury] exposure."

By contrast, Groth splits the 60 fish species in his analysis into five categories of recommended consumption frequency for pregnant women. "The categories are color-coded and ranked based on relative benefit-risk outcomes in the FDA model, not just on [methyl mercury] content, an important distinction," Groth writes.

Groth expands the analysis to look at market share data for the different fish species, noting that the fish contained in his "eat all you like" and "eat often" categories makes up 72 percent of the American seafood market. "On the other hand, the red, "do not eat" and orange, "eat rarely" categories combined make up only 6% of the US seafood market (and more than half of that is one product, canned albacore tuna), but provide more than 40% of total [methyl mercury] exposure," Groth adds. "If women cut back on consuming these varieties, market impacts, except on canned tuna . . . should be minimal."

Groth writes that his analysis "differs most notably from recently issued and proposed government advice by listing 33 specific recommended choices . . . and by providing tiered, nuanced cautionary advice to limit -- not eliminate -- intake of 22 other choices." He cautions that the analysis is limited to

assumptions in the FDA model, and does not consider some of the other contaminants in fish, such as polychlorinated biphenyls, or the cardiovascular benefits of eating fish. -- *Maria Hegstad*

Risk Policy Report - 08/23/2016 , Vol. 23, No. 34

194023

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4301T

Room 5233U

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

To: Wathen, John[Wathen.John@epa.gov]
From: Ex. 6 - Personal Privacy
Sent: Tue 8/23/2016 9:07:34 PM
Subject: Re: FYI: New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

Hi John —
Very interesting article. I guess they are not as worried about people eating "red" fish if they are not women who could get pregnant. Will talk about it when we see you next.

I think we told you that we'll be in Europe Sept. 19 to Oct. 11, seeing Diane and Robert at the end. Between now and then would be interested to hear more about your time in Kentucky.

Tired of heat yet?

Cheers, V

On Aug 23, 2016, at 8:09 AM, Wathen, John <Wathen.John@epa.gov> wrote:

<image001.gif>

Big one I am working on.

~J

From: Conerly, Octavia
Sent: Tuesday, August 23, 2016 8:00 AM
To: OST-EVERYONE <OSTEVERYONE@epa.gov>
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The agencies released a draft update to their joint advisory two years ago, following much prodding from various senators and stakeholders. But the document, which was widely panned by environmentalists concerned that it

encouraged women to eat more fish without providing adequate information about how to avoid methyl mercury, has yet to be finalized.

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The spokeswoman does not specify what type of data is under review. The last draft advisory underwent a peer review by FDA's risk communication federal advisory committee last year, but this new review could address some data about levels of mercury and beneficial oils and fatty acids in various fish species, or a controversial quantitative risk-benefit model for fish consumption that FDA quietly finalized in 2014 along with release of the draft advice, among other topics.

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The advisory aims to inform consumers, particularly pregnant women, on

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Crafting good advice is further complicated because different fish species vary in both mercury levels and levels of beneficial oils. In recent years, some public health experts have sought to use models to better understand the complexity of the risk-benefit scenarios for different fish species.

But FDA's model, released in final form along with the draft advice update, has been highly controversial since a first draft was released for peer review and public comment in 2008. Comments from EPA's National Center for Environmental Assessment were particularly harsh.

The 2014 draft advice recommends that American women eat 8 to 12 ounces of fish per week, and highlights a handful of species to avoid eating because of their high mercury content. But both environmentalists and fishing industry representatives have protested the draft, with environmentalists arguing that the advice opens women up to greater possibility of mercury exposure. Fishing industry representatives, meanwhile, argue that FDA's model, which underlies the advice, shows that it is safe to eat more fish, including particular species like tuna, and that the advice should encourage women to eat more fish.

FDA's model, however, continues to undergo scrutiny. Last year, scientists at state agencies in Connecticut and Minnesota published their own model, which indicated a greater mercury risk than FDA's model, particularly for certain higher mercury species like tuna and swordfish.

Now, Edward Groth III, a former Consumers Union scientist and consultant, has published a new critique of fish consumption risk-benefit models, comparing results from various models with epidemiology studies over recent decades to evaluate the models and try to improve their performance.

"Simply put, it is not a sound policy approach to choose to believe a model and ignore the epidemiological evidence, as the U.S. FDA and EPA have recently proposed to do," Groth concludes in the paper published in*Environmental Research* in August, citing the agencies' draft 2014 advisory. "Disparities between models and epidemiology need to be resolved, so that both types of evidence can be integrated to provide more comprehensive, coherent and scientifically defensible advice."

Groth proposes "align[ing] FDA's model results with recent epidemiological evidence." Groth's analysis results in serving size recommendations for 60 different fish species, which consider both mercury and Omega 3 polyunsaturated fatty acids. "The final serving sizes take advantage of the

model's discriminatory ability but are also consistent with recent epidemiology-based risk and benefit estimates," Groth writes.

Groth argues that by contrast, the agencies' draft advice, which recommends that women eat 8-12 ounces per week of lower mercury fish, but then identifies only four high mercury species to avoid, "offers little practical guidance for consumers and is unlikely to change either fish consumption patterns or [mercury] exposure."

By contrast, Groth splits the 60 fish species in his analysis into five categories of recommended consumption frequency for pregnant women. "The categories are color-coded and ranked based on relative benefit-risk outcomes in the FDA model, not just on [methyl mercury] content, an important distinction," Groth writes.

Groth expands the analysis to look at market share data for the different fish species, noting that the fish contained in his "eat all you like" and "eat often" categories makes up 72 percent of the American seafood market. "On the other hand, the red, "do not eat" and orange, "eat rarely" categories combined make up only 6% of the US seafood market (and more than half of that is one product, canned albacore tuna), but provide more than 40% of total [methyl mercury] exposure," Groth adds. "If women cut back on consuming these varieties, market impacts, except on canned tuna . . . should be minimal."

Groth writes that his analysis "differs most notably from recently issued and proposed government advice by listing 33 specific recommended choices . . . and by providing tiered, nuanced cautionary advice to limit -- not eliminate -- intake of 22 other choices." He cautions that the analysis is limited to assumptions in the FDA model, and does not consider some of the other contaminants in fish, such as polychlorinated biphenyls, or the cardiovascular benefits of eating fish. -- *Maria Hegstad*

Risk Policy Report - 08/23/2016 , Vol. 23, No. 34

194023

Octavia Conerly
Special Assistant to the Office Director
Office of Science and Technology
1200 Pennsylvania Ave. NW MC 4301T
Room 5233U
Washington, DC 20460
EMAIL: conerly.octavia@epa.gov
PHONE: (202) 566-1094
FAX: (202) 566-0441

To: Wathen, John[Wathen.John@epa.gov]
Cc: Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Barash, Shari[Barash.Shari@epa.gov]; Covington, James[Covington.James@epa.gov]
From: Walker, Alice
Sent: Tue 9/27/2016 3:31:03 PM
Subject: RE: Fish Advisory Program

John, Thank you.

From: Wathen, John
Sent: Tuesday, September 27, 2016 9:27 AM
To: Walker, Alice <Walker.Alice@epa.gov>
Cc: Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Covington, James <Covington.James@epa.gov>
Subject: RE: Fish Advisory Program

Alice-

More language on outreach in the fish advisory Program

Fish Advisory Program Outreach

•□□□□□□□ In September of 2014, EPA held the latest in its series of National Fish Forums in Alexandria, Virginia. The Forum was attended by fish advisory staff from all 50 states, several territories, and numerous agencies and academic institutions.

Ex. 5 - Deliberative Process

•□□□□□□□ EPA is new planning for another Fish Forum to be held in 2018. In a recent program review OIG has praised the fish forums and urged EPA to continue holding them.

~John

From: Wathen, John
Sent: Monday, September 26, 2016 4:49 PM
To: Walker, Alice <Walker.Alice@epa.gov>
Cc: Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Covington, James <Covington.James@epa.gov>
Subject: Fish Advisory Program

Alice-

I'm sorry we (James Covington, Samantha Fontenelle, and myself) haven't been successful in providing the information you need for Joel's presentation. Your call was helpful and a conversation would be better, which is what I like to have before providing anyone with information.

Background

Fish consumption advisories is a complex topic and covers a range of activities. Our primary work is providing informational and scientific support to state fish advisory programs. We also work with FDA to provide National advice on fish consumption to reduce exposure to mercury from consuming fish. This primarily focuses on store-bought fish, but also includes a component of advice on fish "caught by friends and family".

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

I hope that this is helpful. We'll talk tomorrow and plug any holes.

~John

John Wathen

Senior Science Advisor, Fish and Beach Programs

National Branch (4305 T)

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Standards and Health Protection Division

Office of Science and Technology

Office of Water

US Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, DC 20460

202-566-0367 phone

202-566-0409 fax

http://www.epa.gov/waterscience

To: Hawkins, Denise[Hawkins.Denise@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Southerland, Elizabeth
Sent: Thur 10/23/2014 1:02:02 PM
Subject: FW: URGENT: PLS SEND ME FINAL QUESTIONS AND AGENDA SO I CAN SHARE NOW WITH EPA. THX
RCAC FINAL Nov 2014 Topic Questions 20OCT2014.doc
DRAFT Day 1 Agenda UPDATED 20OCT14.doc
DRAFT Day 2 Agenda UPDATED 20OCT14.doc

Wanted to make sure I forwarded this to you earlier today. I am having all kinds of computer problems…..

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Wednesday, October 22, 2014 11:31 AM
To: Southerland, Elizabeth
Subject: FW: URGENT: PLS SEND ME FINAL QUESTIONS AND AGENDA SO I CAN SHARE NOW WITH EPA. THX

Betsy,

So glad you are back! Hope you had a good holiday. Good news – we were able to get the necessary MOU so I am now permitted to share the QAs and agenda with you. I'm sure you are flooded with work and so I apologize for having to ask you to please, please review these today if at all possible and let me know if you have any suggestions. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

If there are any immediate issues you want to discuss, please just email me and we'll find time to talk.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Please advise.

Many thanks.

Sharon

To: Hawkins, Denise[Hawkins.Denise@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Southerland, Elizabeth
Sent: Thur 10/23/2014 11:54:52 AM
Subject: Fwd: URGENT: PLS SEND ME FINAL QUESTIONS AND AGENDA SO I CAN SHARE NOW WITH EPA. THX
RCAC FINAL Nov 2014 Topic Questions 20OCT2014.doc
ATT00001.htm
DRAFT Day 1 Agenda UPDATED 20OCT14.doc
ATT00002.htm
DRAFT Day 2 Agenda UPDATED 20OCT14.doc
ATT00003.htm

Sent from my iPhone

Begin forwarded message:

From: "Natanblut, Sharon" <Sharon.Natanblut@fda.hhs.gov>
Date: October 22, 2014 at 6:29:20 PM EDT
To: "Betsy Southerland (southerland.elizabeth@epa.gov)" <southerland.elizabeth@epa.gov>
Subject: FW: URGENT: PLS SEND ME FINAL QUESTIONS AND AGENDA SO I CAN SHARE NOW WITH EPA. THX

Hi Betsy,

Sorry to be a pain. Just wanted to check and see if you had any comments about these materials? Our committee secretary is on my back so we get these final and out of here on Friday.

Many thanks.

Sharon

From: Natanblut, Sharon
Sent: Wednesday, October 22, 2014 11:31 AM
To: Betsy Southerland (southerland.elizabeth@epa.gov)
Subject: FW: URGENT: PLS SEND ME FINAL QUESTIONS AND AGENDA SO I CAN SHARE NOW WITH EPA. THX

Betsy,

So glad you are back! Hope you had a good holiday. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

If there are any immediate issues you want to discuss, please just email me and we'll find time to talk.

Ex. 5 - Deliberative Process

Please advise.

Many thanks.

Sharon

To: Wathen, John[Wathen.John@epa.gov]
Cc: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Kramer, Bill
Sent: Tue 8/23/2016 12:30:52 PM
Subject: RE: FDA-EPA MOU Joint Plan

Excellent. So are you are proposing a venue for consideration of a longer term more inclusive framework that could be presented as an agenda topic for a future FBT meeting to prepare a strategy to develop a plan to develop a Plan?

>< ((('>

Bill Kramer

202-566-0385

From: Wathen, John
Sent: Tuesday, August 23, 2016 8:01 AM
To: Kramer, Bill <Kramer.Bill@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: FDA-EPA MOU Joint Plan

Ex. 5 - Deliberative Process

I agree that consideration of a longer term more inclusive framework is in order.

~John

From: Kramer, Bill
Sent: Tuesday, August 23, 2016 7:55 AM
To: Wathen, John <Wathen.John@epa.gov>
Subject: FDA-EPA MOU Joint Plan

Perhaps we need an agenda topic for the next FBT meeting to prepare a strategy to develop a plan to develop a Plan.

>< ((('>

Bill Kramer

202-566-0385

From: Wathen, John
Sent: Tuesday, August 23, 2016 7:50 AM
To: Kramer, Bill <Kramer.Bill@epa.gov>
Subject: RE: HAB in Crabs Google Alert - shellfish

Can't help you there. To my knowledge, we do not yet have a plan for developing a plan.

~John

From: Kramer, Bill
Sent: Monday, August 22, 2016 2:50 PM
To: Wathen, John <Wathen.John@epa.gov>; Bone, Tracy <Bone.Tracy@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Stahl, Leanne <stahl.leanne@epa.gov>
Subject: RE: HAB in Crabs Google Alert - shellfish

You becha –

The FDA-EPA MOU says a "joint plan" will be developed within six months – can you elaborate?

>< ((('>

Bill Kramer

202-566-0385

From: Wathen, John
Sent: Monday, August 22, 2016 2:46 PM
To: Kramer, Bill <Kramer.Bill@epa.gov>; Bone, Tracy <Bone.Tracy@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Stahl, Leanne <stahl.leanne@epa.gov>
Subject: RE: HAB in Crabs Google Alert - shellfish

Thanks, Bill. I caught a quick glimpse of this on the tube, but did not catch the name of the acid. Remind me to lay off of the domoic acid.

~John

From: Kramer, Bill
Sent: Saturday, August 20, 2016 10:10 AM
To: Bone, Tracy <Bone.Tracy@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Stahl, Leanne <stahl.leanne@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: FW: HAB in Crabs Google Alert - shellfish

>< ((('>

Bill Kramer

202-566-0385

From: Google Alerts [mailto:googlealerts-noreply@google.com]
Sent: Friday, August 19, 2016 9:50 PM
To: Kramer, Bill <Kramer.Bill@epa.gov>
Subject: Google Alert - shellfish

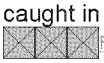
shellfish

As-it-happens update □ August 20, 2016
NEWS

Toxic Rock Crabs: California Department of Public Health

Santa monica Observed

The California Department of Public Health (CDPH) is warning consumers not to eat rock crabs caught in Half Moon Bay and bivalve **shellfish** and rock ...


Flag as irrelevant

See more results | Edit this alert

To: Wathen, John[Wathen.John@epa.gov]
From: Smegal, Deborah
Sent: Fri 7/15/2016 12:10:19 PM
Subject: FW: documents for peer review

Ex. 5 - Deliberative Process

Hi,

Scrolll down to see the files with the peer review charge (6.29.16). We are also sending the excel spreadsheet and have updated the peer review plan that will be posted on our website next week to announce this peer review.

debbie

From: Smegal, Deborah
Sent: Wednesday, June 29, 2016 10:23 AM
To: Jones, William; Larimer, Lisa; Natanblut, Sharon; Wathen, John
Subject: documents for peer review

Hi,

Here are the documents for the peer review package.

Ex. 5 - Deliberative Process

Please let me know if you have any comments/suggestions/edits etc by COB today or sooner. Feel free to edit the peer review plan.

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Smegal, Deborah
Sent: Thur 10/15/2015 6:00:20 PM
Subject: last time to review--need feedback ASAP today
Fish Advice Qs and As-10.15.15.docx
Response to HHS comments 10.15.15.docx
technical web page-fish advice- 10.15.15.docx

Any last comments before I send forward?

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Wathen, John[Wathen.John@epa.gov]
From: Smegal, Deborah
Sent: Thur 10/15/2015 6:21:41 PM
Subject: FW: last time to review--need feedback ASAP today
Fish Advice Qs and As-10.15.15.docx
Response to HHS comments 10.15.15.docx
technical web page-fish advice- 10.15.15.docx

We are all caught up now….any last suggestions—esp on the Q and As? Sharon wanted you to **Ex. 5 - Deliberative Process** If so, I will remove her comment before I send forward. Am keeping the track changes so HHS knows what we changed.

Thx

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Smegal, Deborah
Sent: Thursday, October 15, 2015 2:00 PM
To: Natanblut, Sharon; Jones, William; 'Larimer, Lisa'; Wathen, John
Subject: last time to review--need feedback ASAP today

Any last comments before I send forward?

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Wathen, John[Wathen.John@epa.gov]
Cc: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Natanblut, Sharon
Sent: Thur 7/28/2016 7:09:05 PM
Subject: RE: On another matter

Hi John,

I'm sorry – I haven't been involved in the MOU – who have you been working with? I'm happy to reach out and get an update.

Sharon

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Thursday, July 28, 2016 2:56 PM
To: Natanblut, Sharon
Cc: Larimer, Lisa
Subject: On another matter

Sharon-

Any word on the signing of the MOU?

~John

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, July 28, 2016 2:37 PM
To: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: Fish advice peer review

Ex. 5 - Deliberative Process

From: Smegal, Deborah
Sent: Thursday, July 28, 2016 2:36 PM
To: Jones, William; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Subject: RE: Fish advice peer review

Ex. 5 - Deliberative Process

Lisa and Sharon what do you think?

Debbie

From: Wathen, John <Wathen.John@epa.gov>
Date: July 28, 2016 at 2:11:25 PM EDT
To: Larimer, Lisa <Larimer.Lisa@epa.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>, Jones, William <William.Jones@fda.hhs.gov>
Subject: RE: Fish advice peer review

Thank you, Bill.

Ex. 5 - Deliberative Process

http://www.maine.gov/dhhs/mecdc/environmental-health/eohp/fish/documents/meffguide.pdf

~John

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Thursday, July 28, 2016 2:01 PM
To: Wathen, John <Wathen.John@epa.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Fish advice peer review

I am comfortable getting on board with John's thoughts on this.

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Thursday, July 28, 2016 1:13 PM
To: Smegal, Deborah; Jones, William; Natanblut, Sharon; Larimer, Lisa
Subject: RE: Fish advice peer review

Ex. 5 - Deliberative Process

~John

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, July 28, 2016 12:03 PM

To: Jones, William <William.Jones@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: FW: Fish advice peer review

HI,

What do you think? I need to let them know ASAP.

DEbbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Cowen, Tracey [mailto:TCowen@versar.com]
Sent: Thursday, July 28, 2016 11:13 AM
To: Papadakis, Lori; Smegal, Deborah
Cc: Bottimore, David
Subject: Fish advice peer review

Hi Lori and Debbie,

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Thanks,

Tracey

Tracey L. Cowen

Environmental Scientist

Environmental Services Group

VERSAR

Office: 301-304-3121

Email: tcowen@versar.com

Visit us at: www.versar.com

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]
From: Natanblut, Sharon
Sent: Thur 10/15/2015 12:50:24 PM
Subject: Revised advice -- please review and see if this works for you guys -- we are trying to return to HHS. Thx
FISH_CHART_H_10.13 (2).pdf - Adobe Acrobat Pro.pdf

To: Jones, William[William.Jones@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Natanblut, Sharon
Sent: Wed 10/14/2015 2:24:39 PM
Subject: RE: Revised FISH_CHART-

Thanks Bill. I'll make sure that is added. Lisa or John, will your folks be good with this? We're being pushed to get revised versions to HHS.

Sharon

From: Jones, William
Sent: Wednesday, October 14, 2015 9:26 AM
To: Natanblut, Sharon; Smegal, Deborah; Larimer, Lisa; Wathen, John
Subject: RE: Revised FISH_CHART-

Ex. 5 - Deliberative Process

From: Natanblut, Sharon
Sent: Wednesday, October 14, 2015 8:32 AM
To: Smegal, Deborah; Jones, William; Larimer, Lisa; Wathen, John
Subject: Re: Revised FISH_CHART-

You're right. I'll get that fixed. Thx

Sent from my BlackBerry 10 smartphone.

From: Smegal, Deborah

Sent: Wednesday, October 14, 2015 8:10 AM

To: Natanblut, Sharon; Jones, William; Larimer, Lisa; Wathen, John

Subject: RE: Revised FISH_CHART-

Hi Sharon,

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Regards,

Debbie

From: Natanblut, Sharon
Sent: Tuesday, October 13, 2015 6:41 PM
To: Smegal, Deborah; Jones, William; Larimer, Lisa; Wathen, John
Subject: Revised FISH_CHART-
Importance: High

Hi guys,

Here's the revised fish chart. Please see what you think of this approach. Once we have

agreement on the direction, I'll have the designer spend a little more time on it to tighten it.

Sharon

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Natanblut, Sharon
Sent: Wed 10/14/2015 12:32:23 PM
Subject: Re: Revised FISH_CHART-

You're right. I'll get that fixed. Thx

Sent from my BlackBerry 10 smartphone.

[redacted]

Hi Sharon,

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Regards,

Debbie

From: Natanblut, Sharon

Sent: Tuesday, October 13, 2015 6:41 PM
To: Smegal, Deborah; Jones, William; Larimer, Lisa; Wathen, John
Subject: Revised FISH_CHART-
Importance: High

Hi guys,

Here's the revised fish chart. Please see what you think of this approach. Once we have agreement on the direction, I'll have the designer spend a little more time on it to tighten it.

Sharon

To: Robiou, Grace[Robiou.Grace@epa.gov]
Cc: Wathen, John[Wathen.John@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Bigler, Jeff
Sent: Wed 2/4/2015 2:32:14 PM
Subject: Re: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Left you a vm.

Sent from Jeff Bigler by IPhone

On Feb 4, 2015, at 9:24 AM, "Robiou, Grace" <Robiou.Grace@epa.gov> wrote:

Ex. 5 - Deliberative Process

From: Bigler, Jeff
Sent: Tuesday, February 3, 2015 5:07 PM
To: Wathen, John
Cc: Robiou, Grace; Larimer, Lisa
Subject: Re: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

I agree, and we should ask FTA to explain that next Wednesday.

Sent from Jeff Bigler by IPhone

On Feb 3, 2015, at 4:40 PM, "Wathen, John" <Wathen.John@epa.gov> wrote:

Jeff-

Ex. 5 - Deliberative Process

~John

From: Robiou, Grace
Sent: Tuesday, February 03, 2015 8:44 AM
To: Bigler, Jeff
Cc: Wathen, John; Larimer, Lisa
Subject: Re: Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Thanks. This clarifies it for me. Have a good day!

On Feb 3, 2015, at 8:31 AM, "Bigler, Jeff" <Bigler.Jeff@epa.gov> wrote:

Oh - sorry. My track of time has not been the best.

Ex. 5 - Deliberative Process

Jeff

Sent from Jeff Bigler by IPhone

On Feb 3, 2015, at 7:38 AM, "Robiou, Grace" <Robiou.Grace@epa.gov> wrote:

Jeff,

Two things. First, the call with FDA is next Wednesday, not this week. I didnt schedule it for this week because you said over the weekend that you expected to be back in the office this Thursday. Second, on the call with FDA you said that you had gained access to all thhe comments. Is that not the case?

Please excuse my typos.

On Feb 3, 2015, at 7:21 AM, "Bigler, Jeff" <Bigler.Jeff@epa.gov> wrote:

Grace -

Ex. 5 - Deliberative Process

I should be back in town in time to make the call tomorrow afternoon.

Jeff

Sent from Jeff Bigler by IPhone

On Feb 2, 2015, at 11:37 AM, "Robiou, Grace" <Robiou.Grace@epa.gov> wrote:

> Sharon – I should have included in my email that we have secured some funds to have a contractor (Westat) help us with the response to public comments summary document. The team will decide how a contractor can help, but I thought I would share this piece of good news with you!
>
> Grace
>
> **From:** Robiou, Grace
> **Sent:** Monday, February 02, 2015 11:35 AM
> **To:** 'Natanblut, Sharon'
> **Cc:** Elkin, Ted; Southerland, Elizabeth; Sara Hisel-McCoy; Wathen, John; Bigler, Jeff; Larimer, Lisa; 'william.jones@fda.hhs.gov'; 'deborah.smegal@fda.hhs.gov'
> **Subject:** Proposed Approach/Schedule for Finalizing Joint FDA-EPA Fish Advisory

Sharon,

Good morning. We do not know each other yet, but I was on the phone with you, Betsy Southerland and others last week when we discussed next steps to finalize the joint FDA-EPA fish advisory.

I work with Jeff Bigler, John Wathen, Lisa Larimer, Sara Hisel-Mccoy and Betsy Southerland. Due to Denise's retirement in December and a pending reorganization of our division, John Wathen is serving as the acting Branch Chief between now and April. Starting in April, I will be the branch chief that covers these programs. Jeff, John and Lisa will be in my branch.

Ex. 5 - Deliberative Process

Dr. Williams Jones – FDA/CFSAN (240-402-1422) – William.jones@fda.hhs.gov

Deborah Smegal – FDA/CFSAN (240-402-1818) – Deborah.smegal@fda.hhs.gov

In the past, we have also found Clark Carrington to be a great resource as the keeper of the FDA fish data for mercury. We would like to suggest his inclusion inthe team to work specifically on the binning of the fish for purpose of finalizing the Fish Advisory.

Clark Carrington – FDA/CFSAN (240-402-1947) – clark.carrington@fda.hhs.gov

From EPA, the team would be as follows. We have yet to define roles amongst us, but here is the list with our coordinates.

Jeff Bigler – EPA/Water (202-566-0389) – bigler.jeff@epa.gov

John Wathen – EPA/Water (202-566-0367) – Wathen.john@epa.gov

Lisa Larimer – EPA/Water (202-566-1017) --- Larimer.lisa@epa.gov

Grace Robiou – EPA/Water (202-566-2975) – robiou.grace@epa.gov

EPA proposes to conduct a conference call on Wednesday, February 11, at 1:00pm, for the joint FDA-EPA team t Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Thank you and we look forward to working with you. You can always reach me at 202-566-2975 if you'd like to chat.

Grace Robiou

EPA/ Water

To: Wathen, John[Wathen.John@epa.gov]
From: Conerly, Octavia
Sent: Tue 3/22/2016 2:23:19 PM
Subject: RE: CORRECTION: FYI: Advocates Cite New Mercury Study To Urge Updated EPA, FDA Fish Guide

Yep. That's what I meant to say. Sigh!

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Wathen, John
Sent: Tuesday, March 22, 2016 10:03 AM
To: Conerly, Octavia <Conerly.Octavia@epa.gov>
Subject: RE: CORRECTION: FYI: Advocates Cite New Mercury Study To Urge Updated EPA, FDA Fish Guide

Yep. It's an SHPD thing, Octavia. Lisa Larimer and m'self.

~John

From: Conerly, Octavia
Sent: Tuesday, March 22, 2016 8:25 AM

To: OST-EVERYONE <OSTEVERYONE@epa.gov>
Subject: CORRECTION: FYI: Advocates Cite New Mercury Study To Urge Updated EPA, FDA Fish Guide

It's not EAD that works on this. Sorry, EAD!

Octavia Conerly

Special Assistant to the Office Director

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Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Conerly, Octavia
Sent: Tuesday, March 22, 2016 8:15 AM
To: OST-EVERYONE <OSTEVERYONE@epa.gov>
Subject: FYI: Advocates Cite New Mercury Study To Urge Updated EPA, FDA Fish Guide

FYI. Your colleagues in EAD have been working with FDA on this for quite some time.

Risk Policy Report - 03/22/2016

Advocates Cite New Mercury Study To Urge Updated EPA, FDA Fish Guide

March 21, 2016

The Environmental Working Group is reiterating its call for EPA and the Food and Drug Administration (FDA) to update 2004 guidelines on fish consumption levels, pointing to its new study that concludes pregnant women who follow the existing federal advice could harm their developing fetuses by consuming fish with high levels of mercury.

The study "U.S. Fish Advice May Expose Babies To Too Much Mercury," which EWG and the Mercury Policy Project released March 16, tested the hair of 254 women living in 40 states for mercury. The researchers found that "almost 30 percent" of these women had mercury levels exceeding an EPA exposure guideline of 1 part per million (ppm) which EWG calls outdated and "associated with clear risks to a developing fetus."

Study author Sonya Lunder, a senior analyst with EWG, said in a March 15 interview with *Inside EPA* that the 1 ppm number is extrapolated from EPA's 2001 reference dose (RfD) for methylmercury. EPA describes the RfD of 1x10^-4 milligrams per kilogram bodyweight per day as the maximum amount that it anticipates an individual can eat daily over a lifetime without experiencing adverse effects.

EPA has placed methylmercury on its most recent list of priority contaminants for the agency's Integrated Risk Information System to re-assess in the next few years.

Lunder and others have questioned EPA's RfD in recent years, pointing to newer studies that indicate the RfD is not protective of fetuses, such as a more recent study by Philippe Grandjean and others suggesting that 0.58 ppm is a more appropriate maximum limit for pregnant women. EWG's new study concludes that "nearly 60 percent" of the women it tested exceeded this more stringent benchmark.

The women were selected because they reported eating 2-3 meals of seafood per week, allowing EWG researchers to approximate conditions if federal fish consumption advice were followed. Both the most recent Dietary Guidelines for Americans (DGA), which the Department of Health and Human Services released in January, and the latest draft of EPA and FDA's joint advisory for pregnant women or those who could become pregnant, released in June 2014, recommend consuming no less than 8 ounces of fish per week and no more than 12 ounces.

Since these amounts are significantly larger than the 3.5 ounces of fish per week that national health surveys have shown the average American eats per week, health advocates have charged that EPA and FDA are seeking to increase

women's fish consumption without providing sufficient information on what types of fish they should consume. Different fish species vary widely both in their general levels of mercury and the levels of beneficial oils and fats that they contain. Advocates in the past have praised the latest DGA for providing species-specific recommendations, while cautioning the DGA doesn't provide sufficient advice on fish species to avoid (*Risk Policy Report*, Jan. 12).

EWG and other stakeholders, ranging from members of Congress to the fishing industry, have been pushing the agencies for several years to update their joint advice, last published in 2004. EWG argues that the advice needs to better identify fish species that are low in mercury and high in the beneficial fats and oils for which fish is recommended, particularly to pregnant women. Lunder and colleagues met with congressional staffers to discuss their findings, and are also seeking to schedule briefings with EPA and FDA staff, she said.

"We wanted to test the new draft advice," Lunder said of the study. "We didn't see any difference in hair mercury levels [in women who ate] two or three meals [of fish per week] versus more. That tells us that the species [of fish eaten] are more important than the amount."

Lunder added the DGA "does exactly what we ask for: name high and low mercury fish. The thing they don't address directly is mercury risk for people who eat fish frequently, and they punt to EPA and FDA."

The agencies' joint advice is also designed specifically for pregnant women or those who could become pregnant, while the DGA is a general advice for the population. Mercury is a potent neurotoxin, particularly for the very young, and it contaminates fish in the form of methylmercury. Seafood poses a challenging risk-benefit tradeoff because beneficial oils and fats in seafood boost brain and eye development in the fetus, making it important for pregnant women to eat. The goal is to eat fish species that provide the least risk and the most benefit.

"Our analysis of the women's dietary surveys found that while only a small amount of their mercury intake came from species the government says to avoid or limit, the great majority of the toxin came from species the government does not warn against, especially tuna steaks and tuna sushi," EWG's study says. "And although the women in our study eat more than twice as much fish as the average American, almost 60 percent still don't get the amount of omega-3s recommended during pregnancy from seafood in their diets."

Further, EWG finds that only slightly more than one-quarter "of our participants had both enough omega-3 intake and mercury levels below the EPA exposure guideline of 1 part per million. About one in six had higher levels of mercury and

lower than optimal omega-3s, a particularly unhealthy combination."

The group urges EPA and FDA to update the advisory to "specify the full list of low mercury-high omega-3 fish, such as salmon, that women should add to their diets. This information is already included in the most recent edition of the [DGA] . . . so aligning the recommendations would provide greater clarity to the government's advice . . . The advice should also educate women about the hazards of mercury and name additional species they should limit or avoid for up to a year before conception, such as seabass, halibut and marlin."

EPA and FDA spokesmen provide little insight on the status of the joint advisory. "The FDA and EPA are revising the draft advice," an EPA spokesman writes Inside EPA. "The draft advice was issued in June 2014 to request public comments and since then, we have received over 200 public comments and held a Risk Communication Advisory Committee Meeting in November 2014. We've taken comments into consideration. Based on this information we will update our advice."

An FDA spokesman provided a duplicate statement.

But health advocates and agency sources indicate that multiple retirements among technical experts and key managers working on the advisory has likely delayed its finalization. Neither agency's spokesman responded to questions about the retirements' affect on the advisory, nor to requests for comment on the EWG report.

The report comes as EPA's Inspector General (IG) is conducting a review of the agency's existing public health communication about mercury contamination in fish, begun last fall. A September memo says the review is a discretionary assignment in the IG's fiscal year 2015 annual plan, and will be conducted within the Office of Water, EPA regions, states and tribes.

"The anticipated benefit of this project is to improve the effectiveness of risk communication efforts to ensure the protection of populations most effected by the consumption of mercury-contaminated fish," the memo says (*Risk Policy Report*, Sept. 15).

An IG spokeswoman says the review "is still at the preliminary research phase . . . [IG] program evaluations and audits that progress beyond preliminary research may eventually entail field work, followed by a reporting phase culminating in a final, public report." -- *Maria Hegstad*

Octavia Conerly

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Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

To: Barash, Shari[Barash.Shari@epa.gov]; Buffo, Corey[Buffo.Corey@epa.gov]; Fabiano, Claudia[Fabiano.Claudia@epa.gov]; Hawkins, Denise[Hawkins.Denise@epa.gov]; Keating, Jim[Keating.Jim@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Robiou, Grace[Robiou.Grace@epa.gov]; Wathen, John[Wathen.John@epa.gov]
From: Frey, Sharon
Sent: Wed 9/10/2014 8:26:24 PM
Subject: Friday staff meeting - need your items by tomorrow at 11:00

I'll need changes/additions you have by 11:00 tomorrow. If I don't hear from you, I'll assume you have none.

Based on today's meeting, I have this one topic.

-

-

Draft EPA-FDA Fish Advisory. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Sharon Frey

(202) 566-1480

Office of Science and Technology,

Office of Water, U.S. EPA

To: Wathen, John[Wathen.John@epa.gov]
From: Larimer, Lisa
Sent: Wed 6/29/2016 2:14:38 PM
Subject: RE: seafood advice!

Spoilsport. ☺ You don't believe in celebrating interim milestones?

From: Wathen, John
Sent: Wednesday, June 29, 2016 7:57 AM
To: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: seafood advice!

I am definitely on board with the concept. We have many a hoop to go before our whistles get wet.

~John

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, June 28, 2016 12:23 PM
To: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: seafood advice!

Very exciting!!!

Lisa and John, someday you'll have to share the backstory with us! We'll have to go out for drinks.

From: Smegal, Deborah
Sent: Tuesday, June 28, 2016 12:16 PM
To: Natanblut, Sharon; Jones, William; Larimer, Lisa; Wathen, John
Subject: RE: seafood advice!

Hi,

Ex. 5 - Deliberative Process

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Natanblut, Sharon
Sent: Tuesday, June 28, 2016 12:12 PM
To: Jones, William; Larimer, Lisa; Wathen, John
Cc: Smegal, Deborah
Subject: RE: seafood advice!

Ex. 5 - Deliberative Process

From: Jones, William
Sent: Tuesday, June 28, 2016 12:06 PM

To: Larimer, Lisa; Wathen, John
Cc: Smegal, Deborah; Natanblut, Sharon
Subject: RE: seafood advice!

We just heard that we all have the thumbs up to proceed.

From: Jones, William
Sent: Monday, June 27, 2016 3:13 PM
To: Natanblut, Sharon; Larimer, Lisa; Wathen, John
Cc: Smegal, Deborah
Subject: RE: seafood advice!

Sounds good!

From: Larimer, Lisa <Larimer.Lisa@epa.gov>
Date: June 27, 2016 at 3:03:39 PM EDT
To: Wathen, John <Wathen.John@epa.gov>, Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>, Jones, William <William.Jones@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: seafood advice!

Good sailing winds ahead! **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Friday, June 24, 2016 10:05 AM
To: Wathen, John <Wathen.John@epa.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: seafood advice!

I like the sound of this…fingers are crossed.

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Friday, June 24, 2016 9:58 AM
To: Natanblut, Sharon; Larimer, Lisa
Cc: Smegal, Deborah; Jones, William
Subject: Re: seafood advice!

Ex. 5 - Deliberative Process

Keep your fingers crossed. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

~John

From: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Sent: Thursday, June 23, 2016 5:21 PM
To: Larimer, Lisa; Wathen, John
Cc: Smegal, Deborah; Jones, William
Subject: seafood advice!

Hi guys,

We miss you!!! Have you heard anything from Tom? We sent over the charge questions a week ago – was that shared with you? We still really want to move this forward. Please let us know if you hear anything!!!

Sharon

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]
Cc: Li, Cissy[Cissy.Li@fda.hhs.gov]; Flannery, Brenna[Brenna.Flannery@fda.hhs.gov]; Kim, Grace[Grace.Kim@fda.hhs.gov]; Dennis, Sherri[Sherri.Dennis@fda.hhs.gov]
From: Jones, William
Sent: Thur 8/25/2016 8:41:07 PM
Subject: RE: Summary of Reference provided in the Public comments

WOW!

From: Smegal, Deborah
Sent: Thursday, August 25, 2016 4:01 PM
To: Jones, William; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Cc: Li, Cissy; Flannery, Brenna; Kim, Grace; Dennis, Sherri
Subject: Summary of Reference provided in the Public comments

Hi,

My branch has carefully reviewed the references provided by the public commenters. This has been a major undertaking because in the 222 public comments, 467 unique references were cited. The references were screened for relevance, yielding 319 references that were categorized as shown in this table:

# References	Category
56	Mercury in fish and neurodevelopmental health endpoints
28	Mercury exposure from fish consumption
13	Mercury levels in fish
56	Mercury - other topics, non-neuro health endpoints
9	Other contaminants in fish
24	Fatty acids/omega 3's from fish
4	Other benefits of fish (selenium)
15	Risk-benefit analysis
26	Psychology of fish advice, perception, communication
15	Other groups' fish advice
39	From regulatory agencies (FDA, EPA, etc.)
11	Opinion and commentary
23	Miscellaneous
319	**TOTAL**

Ex. 5 - Deliberative Process

Thanks to Cissy, Brenna, Grace, and Sheila for their hard work!

Regards,

Debbie

Deborah Smegal, MPH
Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis
Office of Analytics and Outreach
CFSAN, FDA
240-402-1818

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Wathen, John[Wathen.John@epa.gov]; Barash, Shari[Barash.Shari@epa.gov]
From: Frey, Sharon
Sent: Thur 8/25/2016 3:22:47 PM
Subject: FW: The Morning Headlines from InsideEPA.com -- August 25, 2016

Not sure if you guys already knew about the article on the joint fish advice. See below

Sharon Frey

Office of Science and Technology

Office of Water

202-566-1480

From: InsideEPA.com [mailto:epa-alerts@iwpnews.com]
Sent: Thursday, August 25, 2016 7:16 AM
To: Frey, Sharon <Frey.Sharon@epa.gov>
Subject: The Morning Headlines from InsideEPA.com -- August 25, 2016

August 25, 2016

Latest News

Peer Reviewers Urge EPA To Add New Approaches To Draft Exposure Guide

Some of the experts who are peer reviewing EPA's proposed update to its 24-year-old human exposure assessment guidelines are pressing the agency to address current and emerging analytical methods, a call which could delay EPA's efforts to quickly finalize the long-running effort to update the guidelines.

News Briefs

District Court Rejects Cities' Claims Against Monsanto For Stormwater PCBs

Appeals Court Seeks Update To EPA Lead Hazard Standards

A federal district court has rejected three California cities' nuisance claims against Monsanto for damages due to polychlorinated biphenyls (PCBs) that the cities claim are present in stormwater, with the court finding that the cities lack a property interest to make the claims.

EPA Sends Controversial Final Pesticide Applicators Rule For OMB Review

EPA has sent for White House Office of Management and Budget (OMB) review its final requirements for certification and training of pesticide applicators, signaling the agency could soon release the controversial rule after state regulators criticized a draft version of the regulation for containing "unworkable provisions."

District Court Rejects Quicker Release Of Tailpipe Air Data

A federal district court has denied a push by pro-ethanol groups to force EPA to accelerate its release of data in response to a Freedom of Information Act (FOIA) request the groups filed over tailpipe emissions, leaving in place its earlier decision that the government can wait until next year before releasing all of the documents.

EPA Increases Burden On States For Tracking Title V Air Permit Objections

EPA is proposing to increase the burden on states for tracking objections to Clean Air Act Title V permits by mandating that states provide written responses to comments on permits they issue under delegated air law authority and submit those records to the agency, which has ultimate power to approve or reject a state-issued permit.

Judge Agrees To Hear EPA-FDA Fish Consumption Advisory Arguments

New Peer Review Further Delays Final EPA/FDA Fish Consumption Advisory

The Food and Drug Administration (FDA) has initiated another peer review related to the joint advisory that EPA and FDA released in 2014 recommending amounts of fish that pregnant women and those who may be pregnant should eat, and a former FDA official says it is unlikely the long-delayed update will be finished before

A federal district court judge has agreed to hold a hearing on a request from environmental and local advocates in Flint, MI, seeking a court order

the end of the year.

Drinking Water Utilities Eye USDA Funds For Source Water Protection

Drinking water utilities are increasingly looking to U.S. Department of Agriculture (USDA) funds to protect source waters from excess nutrients that can come from upstream agricultural activity, with the American Water Works Association (AWWA) hiring consultants to help it examine whether and how such funds can be used.

for the city and state to deliver bottled water water to residents prior to conducting a hearing on the merits of an underlying Safe Drinking Water Act (SDWA) citizen suit.

To: Wathen, John[Wathen.John@epa.gov]
From: Axie N.
Sent: Wed 8/24/2016 10:34:51 PM
Subject: Re: FYI: New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

It's now 6:30 p.m. I'll read this tomorrow morning when my brain is renewed. Now I head over to Hancock point to that good Wednesday evening mtg. Good night my dear.
Ax
Ps- Bixie referred to you soon, " a truly good man - a rare thing.." You're missed up here and I am found lacking that special something. You should have seen Candy's face when I told her it'd just be me for Saturday fish fry. Such disappointment. : -(
Sent from my iPad

On Aug 23, 2016, at 8:09 AM, Wathen, John <Wathen.John@epa.gov> wrote:

<image001.gif>
Big one I am working on.

~J

From: Conerly, Octavia
Sent: Tuesday, August 23, 2016 8:00 AM
To: OST-EVERYONE <OSTEVERYONE@epa.gov>
Subject: FYI: New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

FYI…

New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

August 22, 2016

The Food and Drug Administration (FDA) has initiated another peer review related to the joint advisory that EPA and FDA released in 2014 recommending amounts of fish that pregnant women and those who may be pregnant should eat, though a former FDA source says that it is unlikely the

long-stalled update will be completed before year's end.

The agencies released a draft update to their joint advisory two years ago, following much prodding from various senators and stakeholders. But the document, which was widely panned by environmentalists concerned that it encouraged women to eat more fish without providing adequate information about how to avoid methyl mercury, has yet to be finalized.

Now, FDA is undertaking another peer review of "[t]echnical information on development of fish consumption advice," according to an undated peer review plan posted on FDA's website. The document does not explain exactly what is being peer-reviewed, describing the subject of the review as the "technical information and methodology to support the scientific basis for the fish consumption recommendations," and its purpose as evaluating "methods, data and assumptions." *Relevant documents are available on InsideEPA.com. (Doc. ID: 193972)*

An FDA spokeswoman describes the effort as "a peer review of the appropriateness of the data we are considering employing, the assumptions we are considering making, and the calculations that we are considering using, in developing our updated fish consumption advice."

The spokeswoman does not specify what type of data is under review. The last draft advisory underwent a peer review by FDA's risk communication federal advisory committee last year, but this new review could address some data about levels of mercury and beneficial oils and fatty acids in various fish species, or a controversial quantitative risk-benefit model for fish consumption that FDA quietly finalized in 2014 along with release of the draft advice, among other topics.

The peer review will be of the lowest level of scrutiny, according to the plan, which says it was to be conducted in July. The spokeswoman says that the "peer review will likely be completed this fall, and the results will impact the time frame for completing the final fish consumption advice."

A former FDA source predicts that the advisory will not be finalized until after a new administration is in place, and news of the peer review did not change that impression. "Conducting another peer review of something that is ill defined is a delaying tactic which is par for the course," the source says.

Further delaying finalizing updated advice have been retirements of multiple scientists, managers and staff at both agencies long involved in the fish advisory discussions, as waiting for the new FDA commissioner, Robert

Califf, to become familiar with the issue after being confirmed last February. The source adds that disagreement over the advisory's content has further delayed finalizing the advisory.

EPA last year proposed changes to the 2014 draft, including listing certain species as "do not eat" and others as "eat no more than once per week, but FDA did not list the proposal, the source says. "The gist of what the FDA people were saying [in response] was the proposed changes were completely inconsistent with the [FDA] net benefits [model] . . . there is no basis for the groupings," the source says.

The advisory aims to inform consumers, particularly pregnant women, on what fish to eat and which to avoid to balance the benefits of eating fish, a lean protein containing omega 3 and other beneficial oils that contribute to healthy eye and brain development and protect cardiovascular health, with the risk that fish can contain methyl mercury, a potent neurotoxin. The agencies' earlier fish advisories appear to have led to dramatic reductions in the amount of fish that American women eat, raising concerns that they are missing the many benefits that fish consumption brings.

Crafting good advice is further complicated because different fish species vary in both mercury levels and levels of beneficial oils. In recent years, some public health experts have sought to use models to better understand the complexity of the risk-benefit scenarios for different fish species.

But FDA's model, released in final form along with the draft advice update, has been highly controversial since a first draft was released for peer review and public comment in 2008. Comments from EPA's National Center for Environmental Assessment were particularly harsh.

The 2014 draft advice recommends that American women eat 8 to 12 ounces of fish per week, and highlights a handful of species to avoid eating because of their high mercury content. But both environmentalists and fishing industry representatives have protested the draft, with environmentalists arguing that the advice opens women up to greater possibility of mercury exposure. Fishing industry representatives, meanwhile, argue that FDA's model, which underlies the advice, shows that it is safe to eat more fish, including particular species like tuna, and that the advice should encourage women to eat more fish.

FDA's model, however, continues to undergo scrutiny. Last year, scientists at

state agencies in Connecticut and Minnesota published their own model, which indicated a greater mercury risk than FDA's model, particularly for certain higher mercury species like tuna and swordfish.

Now, Edward Groth III, a former Consumers Union scientist and consultant, has published a new critique of fish consumption risk-benefit models, comparing results from various models with epidemiology studies over recent decades to evaluate the models and try to improve their performance. "Simply put, it is not a sound policy approach to choose to believe a model and ignore the epidemiological evidence, as the U.S. FDA and EPA have recently proposed to do," Groth concludes in the paper published in *Environmental Research* in August, citing the agencies' draft 2014 advisory. "Disparities between models and epidemiology need to be resolved, so that both types of evidence can be integrated to provide more comprehensive, coherent and scientifically defensible advice."

Groth proposes "align[ing] FDA's model results with recent epidemiological evidence." Groth's analysis results in serving size recommendations for 60 different fish species, which consider both mercury and Omega 3 polyunsaturated fatty acids. "The final serving sizes take advantage of the model's discriminatory ability but are also consistent with recent epidemiology-based risk and benefit estimates," Groth writes.

Groth argues that by contrast, the agencies' draft advice, which recommends that women eat 8-12 ounces per week of lower mercury fish, but then identifies only four high mercury species to avoid, "offers little practical guidance for consumers and is unlikely to change either fish consumption patterns or [mercury] exposure."

By contrast, Groth splits the 60 fish species in his analysis into five categories of recommended consumption frequency for pregnant women. "The categories are color-coded and ranked based on relative benefit-risk outcomes in the FDA model, not just on [methyl mercury] content, an important distinction," Groth writes.

Groth expands the analysis to look at market share data for the different fish species, noting that the fish contained in his "eat all you like" and "eat often" categories makes up 72 percent of the American seafood market. "On the other hand, the red, "do not eat" and orange, "eat rarely" categories combined make up only 6% of the US seafood market (and more than half of that is one product, canned albacore tuna), but provide more

than 40% of total [methyl mercury] exposure," Groth adds. "If women cut back on consuming these varieties, market impacts, except on canned tuna . . . should be minimal."

Groth writes that his analysis "differs most notably from recently issued and proposed government advice by listing 33 specific recommended choices . . . and by providing tiered, nuanced cautionary advice to limit -- not eliminate -- intake of 22 other choices." He cautions that the analysis is limited to assumptions in the FDA model, and does not consider some of the other contaminants in fish, such as polychlorinated biphenyls, or the cardiovascular benefits of eating fish. -- *Maria Hegstad*

Risk Policy Report - 08/23/2016 , Vol. 23, No. 34

194023

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4301T

Room 5233U

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

To: Wathen, John[Wathen.John@epa.gov]
From: Natanblut, Sharon
Sent: Wed 3/18/2015 1:06:49 PM
Subject: Re: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.

It was remarkable. What a pleasure working with all of you.

Sharon

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Tuesday, March 17, 2015 03:51 PM
To: Natanblut, Sharon
Subject: RE: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.

Thanks very much, Sharon. Enjoyed our productive day.

~John

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, March 17, 2015 3:04 PM
To: Wathen, John
Subject: Fw: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.

From: Bravo, Luis
Sent: Tuesday, March 17, 2015 01:57 PM
To: Natanblut, Sharon
Cc: Sepe, Daniel
Subject: RE: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.

Here is the PowerPoint.

R/ Luis

From: Natanblut, Sharon
Sent: Tuesday, March 17, 2015 1:47 PM
To: Bravo, Luis
Cc: Sepe, Daniel
Subject: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.

To: Wathen, John[Wathen.John@epa.gov]
From: Natanblut, Sharon
Sent: Tue 3/17/2015 7:03:37 PM
Subject: Fw: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.
RCAC-Nov14TakeAways.pptx

From: Bravo, Luis
Sent: Tuesday, March 17, 2015 01:57 PM
To: Natanblut, Sharon
Cc: Sepe, Daniel
Subject: RE: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.

Here is the PowerPoint.

R/ Luis

From: Natanblut, Sharon
Sent: Tuesday, March 17, 2015 1:47 PM
To: Bravo, Luis
Cc: Sepe, Daniel
Subject: Please help! Im out of thje office -- can you send me the terrific summary document you guys developed on the rcac seafood advice??? In a mtg and could really use it. Thanks tons.

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Shari Barash[sdbarash@verizon.net]
Cc: Wathen, John[Wathen.John@epa.gov]
From: Jones, William
Sent: Wed 8/24/2016 1:40:28 PM
Subject: RE: New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

Thanks

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, August 24, 2016 9:06 AM
To: Smegal, Deborah; Jones, William; Shari Barash
Cc: Wathen, John
Subject: FW: New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

Did you all see this? It's Maria's article.

From: Conerly, Octavia
Sent: Tuesday, August 23, 2016 8:00 AM
To: OST-EVERYONE <OSTEVERYONE@epa.gov>
Subject: FYI: New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

FYI…

New Peer Review Further Delays Final Joint EPA-FDA Fish Advisory (published by InsideEPA)

August 22, 2016

The Food and Drug Administration (FDA) has initiated another peer review related to the joint advisory that EPA and FDA released in 2014 recommending amounts of fish that pregnant women and those who may be pregnant should eat, though a former FDA source says that it is unlikely the long-stalled update will be completed before year's end.

The agencies released a draft update to their joint advisory two years ago, following much prodding from various senators and stakeholders. But the document, which was widely panned by environmentalists concerned that it encouraged women to eat more fish without providing adequate information about how to avoid methyl mercury, has yet to be finalized.

Now, FDA is undertaking another peer review of "[t]echnical information on development of fish consumption advice," according to an undated peer review plan posted on FDA's website. The document does not explain exactly what is being peer-reviewed, describing the subject of the review as the "technical information and methodology to support the scientific basis for the fish consumption recommendations," and its purpose as evaluating "methods, data and assumptions." *Relevant documents are available on InsideEPA.com. (Doc. ID: 193972)*

An FDA spokeswoman describes the effort as "a peer review of the appropriateness of the data we are considering employing, the assumptions we are considering making, and the calculations that we are considering using, in developing our updated fish consumption advice."

The spokeswoman does not specify what type of data is under review. The last draft advisory underwent a peer review by FDA's risk communication federal advisory committee last year, but this new review could address some data about levels of mercury and beneficial oils and fatty acids in various fish species, or a controversial quantitative risk-benefit model for fish consumption that FDA quietly finalized in 2014 along with release of the draft advice, among other topics.

The peer review will be of the lowest level of scrutiny, according to the plan, which says it was to be conducted in July. The spokeswoman says that the "peer review will likely be completed this fall, and the results will impact the time frame for completing the final fish consumption advice."

A former FDA source predicts that the advisory will not be finalized until after a new administration is in place, and news of the peer review did not change that impression. "Conducting another peer review of something that is ill defined is a delaying tactic which is par for the course," the source says.

Further delaying finalizing updated advice have been retirements of multiple scientists, managers and staff at both agencies long involved in the fish advisory discussions, as waiting for the new FDA commissioner, Robert Califf, to become familiar with the issue after being confirmed last February. The source adds that disagreement over the advisory's content has further delayed finalizing the

advisory.

EPA last year proposed changes to the 2014 draft, including listing certain species as "do not eat" and others as "eat no more than once per week, but FDA did not list the proposal, the source says. "The gist of what the FDA people were saying [in response] was the proposed changes were completely inconsistent with the [FDA] net benefits [model] . . . there is no basis for the groupings," the source says.

The advisory aims to inform consumers, particularly pregnant women, on what fish to eat and which to avoid to balance the benefits of eating fish, a lean protein containing omega 3 and other beneficial oils that contribute to healthy eye and brain development and protect cardiovascular health, with the risk that fish can contain methyl mercury, a potent neurotoxin. The agencies' earlier fish advisories appear to have led to dramatic reductions in the amount of fish that American women eat, raising concerns that they are missing the many benefits that fish consumption brings.

Crafting good advice is further complicated because different fish species vary in both mercury levels and levels of beneficial oils. In recent years, some public health experts have sought to use models to better understand the complexity of the risk-benefit scenarios for different fish species.

But FDA's model, released in final form along with the draft advice update, has been highly controversial since a first draft was released for peer review and public comment in 2008. Comments from EPA's National Center for Environmental Assessment were particularly harsh.

The 2014 draft advice recommends that American women eat 8 to 12 ounces of fish per week, and highlights a handful of species to avoid eating because of their high mercury content. But both environmentalists and fishing industry representatives have protested the draft, with environmentalists arguing that the advice opens women up to greater possibility of mercury exposure. Fishing industry representatives, meanwhile, argue that FDA's model, which underlies the advice, shows that it is safe to eat more fish, including particular species like tuna, and that the advice should encourage women to eat more fish.

FDA's model, however, continues to undergo scrutiny. Last year, scientists at state agencies in Connecticut and Minnesota published their own model, which indicated a greater mercury risk than FDA's model, particularly for certain higher mercury species like tuna and swordfish.

Now, Edward Groth III, a former Consumers Union scientist and consultant, has published a new critique of fish consumption risk-benefit models, comparing results from various models with epidemiology studies over recent decades to evaluate the models and try to improve their performance. "Simply put, it is not a sound policy approach to choose to believe a model and ignore the epidemiological evidence, as the U.S. FDA and EPA have recently proposed to do," Groth concludes in the paper published in *Environmental Research* in August, citing the agencies' draft 2014 advisory. "Disparities between models and epidemiology need to be resolved, so that both types of evidence can be integrated to provide more comprehensive, coherent and scientifically defensible advice."

Groth proposes "align[ing] FDA's model results with recent epidemiological evidence." Groth's analysis results in serving size recommendations for 60 different fish species, which consider both mercury and Omega 3 polyunsaturated fatty acids. "The final serving sizes take advantage of the model's discriminatory ability but are also consistent with recent epidemiology-based risk and benefit estimates," Groth writes.

Groth argues that by contrast, the agencies' draft advice, which recommends that women eat 8-12 ounces per week of lower mercury fish, but then identifies only four high mercury species to avoid, "offers little practical guidance for consumers and is unlikely to change either fish consumption patterns or [mercury] exposure."

By contrast, Groth splits the 60 fish species in his analysis into five categories of recommended consumption frequency for pregnant women. "The categories are color-coded and ranked based on relative benefit-risk outcomes in the FDA model, not just on [methyl mercury] content, an important distinction," Groth writes.

Groth expands the analysis to look at market share data for the different fish species, noting that the fish contained in his "eat all you like" and "eat often" categories makes up 72 percent of the American seafood market. "On the other hand, the red, "do not eat" and orange, "eat rarely" categories combined make up only 6% of the US seafood market (and more than half of that is one product, canned albacore tuna), but provide more than 40% of total [methyl mercury] exposure," Groth adds. "If women cut back on consuming these varieties, market impacts, except on canned tuna . . . should be minimal."

Groth writes that his analysis "differs most notably from recently issued and

proposed government advice by listing 33 specific recommended choices . . . and by providing tiered, nuanced cautionary advice to limit -- not eliminate -- intake of 22 other choices." He cautions that the analysis is limited to assumptions in the FDA model, and does not consider some of the other contaminants in fish, such as polychlorinated biphenyls, or the cardiovascular benefits of eating fish. -- *Maria Hegstad*

Risk Policy Report - 08/23/2016 , Vol. 23, No. 34

From: Wathen, John
Location: wiley building--room 2A-023
Importance: Normal
Subject: Accepted: fish advice peer review discussion--in person
Start Date/Time: Mon 9/26/2016 2:00:00 PM
End Date/Time: Mon 9/26/2016 4:00:00 PM

From: Wathen, John
Location: http://epawebconferencing.acms.com/fishadvice/
Importance: Normal
Subject: Declined: Adobe Connect - Meeting Invitation to "Fish advice"
Start Date/Time: Tue 9/13/2016 6:00:00 PM
End Date/Time: Tue 9/13/2016 7:00:00 PM

To: Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]
From: Wathen, John
Sent: Tue 9/13/2016 5:44:44 PM
Subject: RE: Adobe Connect - Meeting Invitation to "Fish advice"

Sam-

Lisa and I have a meeting with FDA that conflicts. Meant to tell you sooner.

~John

-----Original Appointment-----
From: Fontenelle.Samantha@epa.gov [mailto:Fontenelle.Samantha@epa.gov]
Sent: Tuesday, September 13, 2016 1:16 PM
To: Larimer, Lisa; Wathen, John
Subject: Adobe Connect - Meeting Invitation to "Fish advice"
When: Tuesday, September 13, 2016 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: http://epawebconferencing.acms.com/fishadvice/

Please join me in an Adobe Connect Meeting.

Meeting Name: Fish advice
Summary:
Invited By: Samantha Fontenelle (Fontenelle.Samantha@epa.gov (Fontenelle.Samantha@epa.gov)
When: Tuesday 13 September, 02:00 PM - 03:00 PM
Time Zone: (GMT-05:00) Eastern Time (US and Canada) (Please note that Daylight Saving Time (+01:00 hr) is in effect during this time)

To join the meeting:
http://epawebconferencing.acms.com/fishadvice/

If you have never attended an Adobe Connect meeting before:

Test your connection: http://epawebconferencing.acms.com/ http://epawebconferencing.acms.com/common/help/en/support/meeting test.htm

Get a quick overview: http://www.adobe.com/products/ http://www.adobe.com/products/adobeconnect.html

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Mon 9/12/2016 8:29:16 PM
Subject: Technical
technical web page-fish advice 9 12 2016 CXL LLLjw.docx

Lisa-

Sending this to you only. I think I helped it, but see what you think. You may be able to further refine. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

~John

John Wathen

Senior Science Advisor, Fish and Beach Programs

National Branch (4305 **T**)

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Standards and Health Protection Division

Office of Science and **T**echnology

Office of Water

US Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, DC 20460

202-566-0367 phone

202-566-0409 fax

http://www.epa.gov/waterscience

From: Wathen, John
Importance: Normal
Subject: Accepted: fish advice peer reveiw comment discussion
Start Date/Time: Tue 9/13/2016 6:00:00 PM
End Date/Time: Tue 9/13/2016 7:00:00 PM

From: Wathen, John
Importance: Normal
Subject: Accepted: fish advice peer review comment discussion
Start Date/Time: Wed 9/21/2016 3:00:00 PM
End Date/Time: Wed 9/21/2016 4:00:00 PM

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Tue 1/10/2017 5:54:09 PM
Subject: RE: do you have the remarks from the media call from a previous FDA-EPA fish advice release?

No I don't. Before my time, and Jeff didn't leave me any treasures.

~John

From: Larimer, Lisa
Sent: Tuesday, January 10, 2017 12:11 PM
To: Wathen, John <Wathen.John@epa.gov>
Subject: do you have the remarks from the media call from a previous FDA-EPA fish advice release?

Especially Betsy's remarks, if she was the one talking on behalf of EPA.

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Fri 1/6/2017 4:09:48 PM
Subject: Re: Seafood Advice

By the way, who was the contractor?

~John

From: Larimer, Lisa
Sent: Friday, January 6, 2017 10:02 AM
To: Wathen, John
Subject: RE: Seafood Advice

Ex. 5 - Deliberative Process

From: Wathen, John
Sent: Friday, January 06, 2017 9:37 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Re: Seafood Advice

Looks good, Lisa. I assume there's a person in the process that inserts a new docket number.

Ex. 5 - Deliberative Process

~John

From: Larimer, Lisa
Sent: Thursday, January 5, 2017 6:11 PM
To: Campbell, Ann
Cc: Barash, Shari; Southerland, Elizabeth; Hisel-Mccoy, Sara; Wathen, John
Subject: RE: Seafood Advice

Ex. 5 - Deliberative Process

From: Campbell, Ann
Sent: Thursday, January 05, 2017 6:01 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Barash, Shari <Barash.Shari@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Re: Seafood Advice

Thanks Lisa. Re the content of the advice itself. Has any of the substance changed since the last time Joel was briefed? Can I get the FRN for Joel to look at? Thanks!

On Jan 5, 2017, at 5:55 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

> FDA and EPA have been working collaboratively on the materials for the fish advice. Folks are still working on redesigned web pages, scripts for the media call and outreach to stakeholder groups, but the documents associated with the advice (e.g., chart with the fish types and recommended consumption frequency, Q&A, *Federal Register* notice) are ready to go. The web pages could be ready early next week; Travis Loop would know when the communication materials could be ready.
>
> **From:** Campbell, Ann
> **Sent:** Thursday, January 05, 2017 4:48 PM
> **To:** Barash, Shari <Barash.Shari@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
> **Cc:** Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
> **Subject:** RE: Seafood Advice
>
> Thanks Shari. I'll keep an eye out for it.

From: Barash, Shari
Sent: Thursday, January 05, 2017 4:48 PM
To: Campbell, Ann <Campbell.Ann@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: Seafood Advice

Thanks Ann. Lisa Larimer will send you something shortly.

Shari Z. Barash

Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Campbell, Ann
Sent: Thursday, January 05, 2017 4:43 PM
To: Barash, Shari <Barash.Shari@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: Seafood Advice

Great news! He will be on board. I will let him know that the call is coming. If you all could send a brief email summarizing the content of where we're at for awareness, I think that would be great.

From: Barash, Shari
Sent: Thursday, January 05, 2017 4:30 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: Seafood Advice

I assume Joel is sufficiently prepped to say: YES!!

But if there is anything we need to do to make sure that happens, please tell us.

Shari Z. Barash

Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Southerland, Elizabeth
Sent: Thursday, January 05, 2017 4:17 PM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: RE: Seafood Advice

Just got a message from Sharon Natanblut who is on vacation now. She left me a voice message that Jeremy Sharp will be calling Joel today and ask for a final reassurance that EPA is excited about getting the advice out in the next 10 days!!! According to my calculation, that would mean Jan. 16. Of course, Joel knows we have all been lighting the expensive $2 candles praying for release of the advice asap. Looks like all that fire power has worked……

From: Hisel-Mccoy, Sara
Sent: Thursday, January 05, 2017 12:31 PM
To: Campbell, Ann <Campbell.Ann@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Subject: RE: Seafood Advice

Ann,

It is feeling surreal. So, our POC at FDA, Sharon Natanblut has a meeting with her Deputy Commissioner for Policy this afternoon to discuss fish advice. We will know more after we hear about how that discussion goes. We have no word on OMB discussions.

From: Campbell, Ann
Sent: Thursday, January 05, 2017 12:15 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Subject: Seafood Advice

Any word on where this stands?

To: Axie N Ex. 6 - Personal Privacy
From: Wathen, John
Sent: Thur 1/5/2017 9:39:23 PM
Subject: Climate CHange

Links to the whole report- pretty complete and interesting.

We hear that the mercury fish advice is in motion…

~Buster

https://www.epa.gov/climate-indicators/downloads-indicators-report

John Wathen

Senior Science Advisor, Fish and Beach Programs

National Branch (4305 T)

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Standards and Health Protection Division

Office of Science and Technology

Office of Water

US Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, DC 20460

202-566-0367 phone

202-566-0409 fax

http://www.epa.gov/waterscience

To: Barash, Shari[Barash.Shari@epa.gov]
Cc: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Thur 1/5/2017 9:36:15 PM
Subject: FW: Fish advice: Communications channels are in place

I assume Lisa shared this with you.

~John

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Tuesday, January 03, 2017 1:29 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Cc: Wathen, John <Wathen.John@epa.gov>
Subject: RE: Fish advice: Communications channels are in place

I heard this morning that folks at our end were to have a call today to find out where it stands.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, January 03, 2017 1:16 PM
To: Natanblut, Sharon; Smegal, Deborah; Jones, William
Cc: Wathen, John
Subject: Fish advice: Communications channels are in place

I've heard that EPA's communications folks are now hooked up with FDA's and are directly coordinating on the communications materials and release plan for the fish advice. So that part's in place. Any other news?

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Tue 12/6/2016 8:16:10 PM
Subject: RE: changes made to fish advice chart and Q&A in response to HHS comments

Well, it's true. I just looked at the chart and did not read the email. Sigh.

From: Larimer, Lisa
Sent: Tuesday, December 06, 2016 3:14 PM
To: Wathen, John <Wathen.John@epa.gov>
Subject: RE: changes made to fish advice chart and Q&A in response to HHS comments

The email said:

Uncorrected chart is attached: changes to be made to chart include:

(1) In the footnote, **Ex. 5 - Deliberative Process**

(2) Switch the EPA logo to the one that says Environmental Protection Agency on the side to more closely mirror the logo FDA is using.

From: Wathen, John
Sent: Tuesday, December 06, 2016 3:05 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: changes made to fish advice chart and Q&A in response to HHS comments

It's still in the footnote.

~John

From: Larimer, Lisa
Sent: Tuesday, December 06, 2016 3:04 PM
To: Wathen, John <Wathen.John@epa.gov>
Subject: RE: changes made to fish advice chart and Q&A in response to HHS comments

What did you think was happening?

From: Larimer, Lisa
Sent: Tuesday, December 06, 2016 3:02 PM
To: Wathen, John <Wathen.John@epa.gov>
Subject: RE: changes made to fish advice chart and Q&A in response to HHS comments

Right, we are **Ex. 5 - Deliberative Process**

From: Wathen, John
Sent: Tuesday, December 06, 2016 3:01 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: changes made to fish advice chart and Q&A in response to HHS comments

I thought we Ex. 5 - Deliberative Process

~John

From: Larimer, Lisa
Sent: Tuesday, December 06, 2016 2:50 PM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>

Cc: Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>
Subject: FYI: changes made to fish advice chart and Q&A in response to HHS comments

Track changes version of Q&A attached.

Uncorrected chart is attached: changes to be made to chart include:

(1) In the footnote, **Ex. 5 - Deliberative Process**

(2) Switch the EPA logo to the one that says Environmental Protection Agency on the side to more closely mirror the logo FDA is using.

Will let you know as soon as I hear from FDA on next steps.

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Tuesday, December 06, 2016 10:24 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>
Cc: Wathen, John <Wathen.John@epa.gov>
Subject: RE: We have translations!

Hi,

The chart changes: **Ex. 5 - Deliberative Process**

Latest Q and A's with track changes is attached.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Monday, December 05, 2016 10:51 PM
To: Natanblut, Sharon; Smegal, Deborah; Jones, William
Cc: Wathen, John
Subject: We have translations!

We have the chart text and Q&A translated into Ex. 5 - Deliberative Process Other languages forthcoming. Let me know what changes are made to the chart and Q&A so I can make sure the translations are changed too. . .

Lisa Larimer, P.E.
202-566-1017

U.S. Environmental Protection Agency, Washington, DC
Office of Water, Standards and Health Protection Division
www.epa.gov/learn-issues/learn-about-water

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Tue 9/29/2015 5:59:12 PM
Subject: RE: Fish advice Q&A and technical page

OK

From: Larimer, Lisa
Sent: Tuesday, September 29, 2015 1:58 PM
To: Hisel-Mccoy, Sara; Barash, Shari; Wathen, John
Subject: RE: Fish advice Q&A and technical page

I've already started pulling info from emails on most of these. John, can you help with #5?

Sara, were you thinking a PowerPoint presentation?

From: Hisel-Mccoy, Sara
Sent: Tuesday, September 29, 2015 1:51 PM
To: Barash, Shari; Larimer, Lisa; Wathen, John
Subject: RE: Fish advice Q&A and technical page

Shari,

Thank you! I agree with what you have. Additionally I think we need to at least touch on the Ex. 5 - Deliberative Process I have cut and pasted her earlier message below and included updated thoughts (mine) in red. Also, since some were in your list, Shari, I just included the different ones below (5 and 6)

Here is what we will need for the Thursday meeting with Tom Burke.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Barash, Shari
Sent: Tuesday, September 29, 2015 12:42 PM
To: Hisel-Mccoy, Sara; Larimer, Lisa; Wathen, John
Subject: RE: Fish advice Q&A and technical page

If it's helpful for creating categories for the briefing, my notes had the following as Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Of course, Lisa has provided most of the responses to these issues in the various email notes that could be pulled into the briefing (at least as attachments).

Shari

Shari Z. Barash

Acting Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Hisel-Mccoy, Sara
Sent: Tuesday, September 29, 2015 12:04 PM
To: Larimer, Lisa; Wathen, John; Barash, Shari
Subject: Fwd: Fish advice Q&A and technical page

OK so we need briefing materials Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa please just pass through the beach ICR to Menchu. don't take the time to look at that. we need to focus on the briefing Ex. 5 - Deliberative Process We will be able to make changes to the icr on the final one.

Thanks.

Sara Hisel-McCoy

Standards and Health Protection Division

202 566-1649

Begin forwarded message:

From: "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Date: September 29, 2015 at 11:58:14 AM EDT
To: "Hisel-Mccoy, Sara" <Hisel-McCoy.Sara@epa.gov>
Cc: "Larimer, Lisa" <Larimer.Lisa@epa.gov>, "Wathen, John" <Wathen.John@epa.gov>, "Barash, Shari" <Barash.Shari@epa.gov>
Subject: Re: Fish advice Q&A and technical page

Damn, we keep getting people changing! HHS briefing is now on Friday so we should proceed with the Thursday meeting.

Sent from my iPhone

On Sep 29, 2015, at 10:51 AM, Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov> wrote:

Betsy,

So, just a quick status update – we have not heard back from Sharon today at all. Kacee called though to follow up. Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process She is going out of town and will be giving me someone else to work with in her absence.

Sar

From: Hisel-Mccoy, Sara
Sent: Tuesday, September 29, 2015 11:48 AM
To: Deener, Kathleen
Cc: Fegley, Robert; Southerland, Elizabeth; Hauchman, Fred; Larimer, Lisa
Subject: Fish advice Q&A and technical page

Kacee,

Attached are the latest Q&As and Technical Page. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Please let me know who we should coordinate with while your are out of town.

Thanks much, Sara

From: Larimer, Lisa
Sent: Tuesday, September 29, 2015 11:34 AM
To: Hisel-Mccoy, Sara
Subject: fish advice Q&A

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Wathen, John
Location: DCRoomWest5233B/DC-CCW-OST
Importance: Normal
Subject: Accepted: Next Steps on Fish Advice
Start Date/Time: Thur 10/1/2015 3:00:00 PM
End Date/Time: Thur 10/1/2015 4:00:00 PM

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Barash, Shari[Barash.Shari@epa.gov]
From: Wathen, John
Sent: Fri 11/18/2016 3:13:05 PM
Subject: Re: ICMGP 2017 – Conference Reminders

Absolutely, but I have not yet ginned. Maybe over the course of the next week if I get stuck inside with bad weather in VT, but no later than say early the week of the 28th so we can send it around that week. Abstracts don't take long, presentations take longer, and papers take forever.

~John

From: Larimer, Lisa
Sent: Friday, November 18, 2016 9:06 AM
To: Wathen, John; Barash, Shari
Subject: RE: ICMGP 2017 – Conference Reminders

John, are you still ginning up an abstract in case we get the fish advice out by the abstract submission deadline?

From: Wathen, John
Sent: Friday, November 18, 2016 7:59 AM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Subject: Fw: ICMGP 2017 – Conference Reminders

FYI-

~John

From: Mccann, Ellie
Sent: Thursday, November 17, 2016 5:34 PM
To: Ankrah, Rodges; Aranda, Amber; Bailey, Marianne; Barr, Linda; Bash, Jesse; Vauter, Ben; Blackburn, Elizabeth; Brinkhuis, Randall; Burton, Laureen; Camacho, Iris; Chemerys, Ruth; Cuje, Jace; Cybulski, Walter; Dibble, Christine; Durkee, Stanley; Edmonds, Marc; Firestone, Michael; French, Chuck; Golden, Heather; Groeneveld, Thomas; Helms, Greg; Hetes, Bob;

Highsmith, Damon; Hutson, Nick; Itkin, Cheryl; Jackson, Mary; Jordan, Ronald; Knightes, Chris; Koch, Erin; Kryak, DavidD; Kurlansky, Ellen; Lacy, Gail; Lehman, Timothy; Matthai, Paul; Mazza, Carl; McKinney, Doug; Nichols, Nick; O'Mara, Kate; Randall, Paul; Roberts, Cindy; Rodia, Monica; Saltman, Tamara; Schappelle, Seema; Serre, Shannon; Singhvi, Raj; Adrian, Stephanie; Stroup, Gene; Strum, Madeleine; Vette, Alan; Wathen, John; Wayland, Robertj; Wen, Chen; Woodall, George; Zaragoza, Larry; Bertram, Gary; Cain, Alexis; Casso, Ruben; Eckley, Chris; Fisher, Jacqueline; Fleck, Diane; Gillam, Rick; Langenfeld, Matthew; Lugo, Lizette; Maddaloni, Mark; McClain-Vanderpool, Lisa; Mitchell, Ken; Narvaez, Madonna; Orlando, Danny; Ott, Toney; Piergiovanni, Peter; Quinn, Elizabeth; Rajagopalan, Latha; Stewart, Kathleen; Tomes, Wendell; Weisinger, Keith; Weiss, Jeri; Winfield, Richard; Woodruff, Leigh
Cc: Lewis, Clarence; Mccann, Ellie; Winchester, Erik; Edmonds, Marc; Slotnick, Sue; Groeneveld, Thomas
Subject: FW: ICMGP 2017 – Conference Reminders

EPA Hg coordination group - FYI

~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

Ellie McCann

Senior Policy Advisor

Office of Pollution Prevention & Toxics

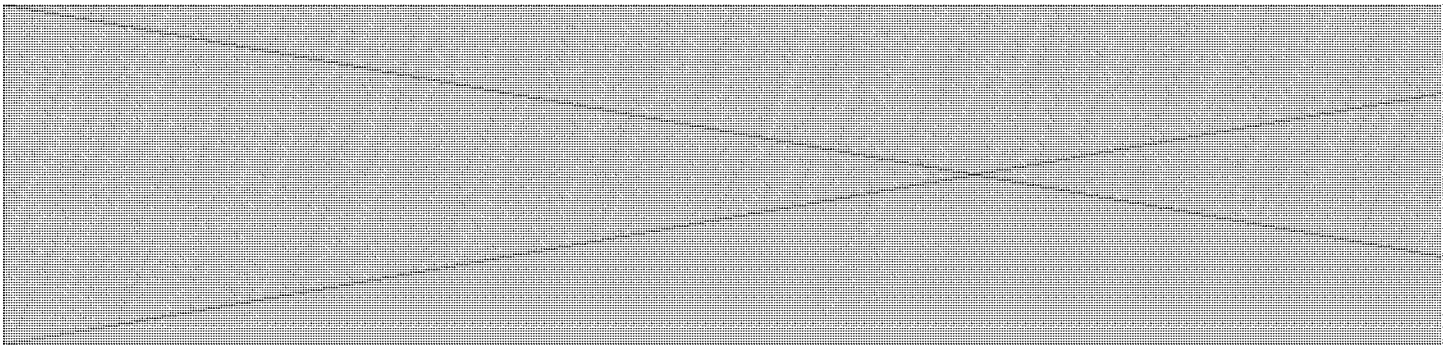
US Environmental Protection Agency

1200 Pennsylvania Ave. NW

Washington, DC 20460

202-566-0520

From: Mercury Conference 2017 [mailto:Mercury2017@agendamanagers.com]
Sent: Thursday, November 17, 2016 5:32 PM
To: Mccann, Ellie <Mccann.Ellie@epa.gov>
Subject: ICMGP 2017 – Conference Reminders
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~



Update from the 13th International Conference on Mercury as a Global Pollutant

REMINDER: CALL FOR ABSTRACTS! The Executive Committee of the International Conference on Mercury as a Global Pollutant 2017 (ICMGP 2017) invites you to share your work, ideas, research, and challenges by submitting an abstract related to the **themes and topics** of the conference. For more details and to submit an abstract, click **here**. **SUBMIT NOW - DEADL INE IS DECEMBER 15, 2016.**

REMINDER: Nominate someone for the *Kathryn R. Mahaffey Lifetime Achievement Award in Mercury Research*! This award was established in 2011 to celebrate and recognize select individuals who have made extraordinary lifetime achievements in mercury research, mentoring, and/or contributions to governmental policy and public outreach. **NOMINATIONS ARE DUE NOVEMBER 30, 2016**. Furthered details are **here.**

If you are interested in becoming a **sponsor or exhibitor** of the conference, please take note of our most up-to-date **sponsorship and exhibit details**. For more information please contact the Conference Secretariat at **Mercury2017@agendamanagers.com.**

Please bookmark and visit the conference website often – you will find us at mercury2017.com! We will be adding content regularly over the course of our planning between now and July 2017.

We look forward to seeing you in Providence!

Your Co-Chairs:

Charley Driscoll & Celia Chen

.

Please feel free to forward this e-mail to anyone who might be interested in the conference but is not yet on our electronic mailing list.

Cc: Barash, Shari[Barash.Shari@epa.gov]
To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]
From: Wathen, John
Sent: Fri 11/4/2016 12:48:17 PM
Subject: Re: Translating Fish Advice into other languages

No Wikipedia bashing here.

~John

From: Larimer, Lisa
Sent: Thursday, November 3, 2016 5:07 PM
To: Fontenelle, Samantha
Cc: Barash, Shari; Wathen, John
Subject: RE: Translating Fish Advice into other languages

If we're going for most bang for the buck, Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process is spoken in quite a few countries as well.

OK, rather than me guessing, here's what World Atlas and wikipedia (I know, I know) had to say (see below). Similar results.

I think my vote is for

Ex. 5 - Deliberative Process

Most US Native Speakers By Language (world atlas)

Rank	Primary Language Spoken at Home in the US	Number of

		speakers
1	English	231,122,908
2	Spanish	37,458,470
3	Chinese (incl. Cantonese, Mandarin, other Chinese languages)	2,896,766
4	French and French Creole	2,047,467
5	Tagalog	1,613,346
6	Vietnamese	1,399,936
7	Korean	1,117,343
8	German	1,063,773
9	Arabic	924,374
10	Russian	879,434
11	Italian	708,966
12	Portuguese	693,469
13	Hindi	643,337
14	Polish	580,153
15	Japanese	449,475
16	Urdu	397,502
17	Persian	391,113
18	Gujarati	373,253
19	Greek	304,932
20	Bengali	257,740
21	Panjabi	253,740
22	Telugu	247,760
23	Armenian	237,840
24	Hmong	214,943
25	Hebrew	212,747

Wikipedia:

According to the American Community Survey 2011, endorsed by the United States Census Bureau, the languages spoken at home with over 100,000 speakers older than five are:

1. English – 230 million
2. Spanish – 37.58 million
3. Chinese – 2.88 million (mainly Yue dialects such as Cantonese and Taishanese, Standard Mandarin Chinese, also Hokkien, Hakka)
4. French – 1.30 million + 750,000 French Creole
5. Tagalog – 1.59 million + (Most Filipinos also know other Philippine languages, e.g. Ilokano, Pangasinan, Bikol languages, and Visayan languages.)
6. Vietnamese – 1.41 million
7. Korean – 1.14 million
8. German – 1.08 million (High/Standard German) + (May include German dialects like Pennsylvania German, Hutterite German, Plautdietsch, Texas German)
9. Arabic – 951,700

10. Russian – 905,800
11. Other Indic languages – 815,345 (Includes Punjabi,Marathi)
12. Bengali- 800,000 [14][15][16]
13. Italian – 723,600
14. Portuguese – 673,500
15. Hindi – 648,900
16. Polish – 607,500
17. Japanese – 436,100
18. Persian – 407,600
19. Urdu – 373,800
20. Gujarati – 358,400
21. Greek – 304,900
22. Serbo-Croatian – 269,600
23. Armenian – 246,900
24. Hebrew – 216,300
25. Khmer – 212,500
26. Hmong - 211,200
27. Navajo – 169,300
28. Thai - 163,200
29. Yiddish - 160,900
30. Laotian - 140,900
31. Tamil - 132,573
32. Nepali language - 185,145

From: Fontenelle, Samantha
Sent: Thursday, November 03, 2016 4:22 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Translating Fish Advice into other languages

Hi Lisa,

We prepared brochures on the 2004 advice in the following foreign languages:

- □□□□□□□ Spanish
- □□□□□□□ Chinese
- □□□□□□□ Korean
- □□□□□□□ Portuguese
- □□□□□□□ Vietnamese

•□□□□□□□ Cambodian

•□□□□□□□ Hmong

Looking at what languages the EPA's website has been translated into they include: Spanish, Chinese (simplified and traditional), Korean, and Vietnamese. In talking to Cara, she indicated that MN had suggested that we include Ex. 5 - Deliberative Process was suggested at the time but I guess the decision was made not to include them. Suggest we ask **Ex. 5 - Deliberative Process** for input on languages we should include or drop from our current list. We can also ask if they could suggest entities that provide excellent translation services in case the Agency translation contractor does not have expertise in a particular language.

Ex. 5 - Deliberative Process

Cara thinks in terms of translation services, that the Agency's contractor may be able to translate in these languages and at a minimum the ones shown on the Agency website.

This may be more info than you need but hope it helps.

CDR Samantha Fontenelle

US Public Health Service Commissioned Corps

USEPA, Office of Water

Standards and Health Protection Division

1301 Constitution Ave, NW

Washington, DC 20460

Room-5231X, MC-4305T

202-566-2083 (phone)

(202) 566-0409 (fax)

To: Christensen, Christina[Christensen.Christina@epa.gov]
From: Wathen, John
Sent: Tue 11/1/2016 8:06:56 PM
Subject: RE: Discuss fish advice communications needs

Thanks!

From: Christensen, Christina
Sent: Tuesday, November 01, 2016 4:06 PM
To: Wathen, John <Wathen.John@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Discuss fish advice communications needs

Just updated the calendar invite with a call in number.

From: Wathen, John
Sent: Tuesday, November 01, 2016 4:04 PM
To: Christensen, Christina <Christensen.Christina@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Discuss fish advice communications needs

Christina-

I am teleworking tomorrow AM, but if you'll open up a line, I'll call in.

~John

-----Original Appointment-----
From: Christensen, Christina
Sent: Tuesday, November 01, 2016 3:57 PM
To: Larimer, Lisa; Barash, Shari; Fontenelle, Samantha; Wathen, John; Lalley, Cara; Gerstein, Arielle
Subject: Discuss fish advice communications needs
When: Wednesday, November 02, 2016 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest6105ERockCreek/DC-EPA-West-OST

Setting up time to discuss communications needs for EPA/FDA fish advice.

From: Wathen, John
Location: DCRoomWest6105ERockCreek/DC-EPA-West-OST
Importance: Normal
Subject: Tentative: Discuss fish advice communications needs
Start Date/Time: Wed 11/2/2016 2:00:00 PM
End Date/Time: Wed 11/2/2016 3:00:00 PM

To: Christensen, Christina[Christensen.Christina@epa.gov]
Cc: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Tue 11/1/2016 8:03:47 PM
Subject: RE: Discuss fish advice communications needs

Christina-

I am teleworking tomorrow AM, but if you'll open up a line, I'll call in.

~John

-----Original Appointment-----
From: Christensen, Christina
Sent: Tuesday, November 01, 2016 3:57 PM
To: Larimer, Lisa; Barash, Shari; Fontenelle, Samantha; Wathen, John; Lalley, Cara; Gerstein, Arielle
Subject: Discuss fish advice communications needs
When: Wednesday, November 02, 2016 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest6105ERockCreek/DC-EPA-West-OST

Setting up time to discuss communications needs for EPA/FDA fish advice.

To: Hawkins, Denise[Hawkins.Denise@epa.gov]
From: Wathen, John
Sent: Tue 8/19/2014 12:51:20 PM
Subject: RE: Children's Health Protection Advisory Committee

I agree that the charge is OK.

~John

From: Hawkins, Denise
Sent: Tuesday, August 19, 2014 8:40 AM
To: Southerland, Elizabeth
Cc: Wathen, John; Bigler, Jeff; Hisel-Mccoy, Sara; Washington, Evelyn
Subject: RE: Children's Health Protection Advisory Committee

No, no issues with the charge.

From: Southerland, Elizabeth
Sent: August 18, 2014 5:48 PM
To: Hawkins, Denise
Cc: Wathen, John; Bigler, Jeff; Hisel-Mccoy, Sara; Washington, Evelyn
Subject: Re: Children's Health Protection Advisory Committee

So you have no concerns about the charge? If not, I will get back to her tomorrow morning and say Jeff will do the background briefing.

Sent from my iPhone

On Aug 18, 2014, at 5:39 PM, "Hawkins, Denise" <Hawkins.Denise@epa.gov> wrote:

> **As long as it's a background briefing and they prepare their comments independently, I'm ok with this. I think Jeff should do the briefing. (In fact, he already did one for CHPAC.)**
>
> **From:** Southerland, Elizabeth
> **Sent:** August 18, 2014 5:30 PM

To: Hawkins, Denise; Wathen, John; Bigler, Jeff; Hisel-Mccoy, Sara; Washington, Evelyn
Subject: Fwd: Children's Health Protection Advisory Committee

I am fine with the charge. Do you have concerns? Who could do the presentation?

Sent from my iPhone

Begin forwarded message:

From: "Reed, Khesha" <Reed.Khesha@epa.gov>
Date: August 18, 2014 at 5:27:17 PM EDT
To: "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Subject: RE: Children's Health Protection Advisory Committee

Betsey,

I heard back from FDA. They are fine with CHPAC providing advice on the Fish Advisory. They even approved the charge!

Ex. 5 - Deliberative Process

We are behind schedule in finalizing the agenda, so a quick response would be greatly appreciated.

Please give me a call if you have questions. Thanks for your help.

Khesha Reed

Acting Director

Office of Children's Health Protection

Environmental Protection Agency
1200 Pennsylvania Ave, NW
Mailcode 1107T
Washington, DC 20460

(202) 566-0594

From: Reed, Khesha
Sent: Thursday, August 14, 2014 7:03 PM
To: Southerland, Elizabeth
Subject: Re: Children's Health Protection Advisory Committee

Ex. 5 - Deliberative Process

Hopefully I'll hear back from her tomorrow. I really need to finalize the agenda.

I'll keep you informed.

Sent from my iPhone

On Aug 14, 2014, at 3:35 PM, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov> wrote:

Ex. 5 - Deliberative Process

From: Reed, Khesha
Sent: Thursday, August 14, 2014 2:23 PM
To: Southerland, Elizabeth
Subject: FW: Children's Health Protection Advisory Committee

Betsey,

Ex. 5 - Deliberative Process

Feel free to give me a call if you need more info or want to discuss.

Thanks,

Khesha Reed

Acting Director

Office of Children's Health Protection

Environmental Protection Agency
1200 Pennsylvania Ave, NW
Mailcode 1107T
Washington, DC 20460

(202) 566-0594

From: Reed, Khesha
Sent: Tuesday, August 12, 2014 5:19 PM
To: 'Natanblut, Sharon'
Subject: RE: Children's Health Protection Advisory Committee

Sharon,

I appreciate you getting back to me quickly and again apologize for missing your original response. I have answered your questions (below in green). Please feel

free to give me a call if you have additional questions or need clarification.

Thanks,

Khesha Reed

Acting Director

Office of Children's Health Protection

Environmental Protection Agency
1200 Pennsylvania Ave, NW
Mailcode 1107T
Washington, DC 20460

(202) 566-0594

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Monday, August 11, 2014 3:32 PM
To: Reed, Khesha
Subject: RE: Children's Health Protection Advisory Committee

If you could provide the first two items right away, and follow-up with the others, we'd really appreciate it. I did a quick check and didn't see the FR notice.

Thanks.

Sharon

From: Natanblut, Sharon
Sent: Monday, August 11, 2014 3:28 PM
To: 'Reed, Khesha'
Subject: RE: Children's Health Protection Advisory Committee

Hi Khesha,

We do have several requests for information with regard to the September meeting and would greatly appreciate if you could provide the following:

1. the FR notice issued about the September meeting (as well as any other info made public about this meeting) – Here's the link to the FR notice http://www.gpo.gov/fdsys/pkg/FR-2014-08-11/html/2014-18931.htm. This notice and a meeting announcement on our website http://www2.epa.gov/children/childrens-health-protection-advisory-committee-chpac are the only sources of public information about the meeting.

2. the list of questions you are planning to ask the committee to consider. This is a draft charge based on the FRN. We will work with you and the EPA Office of Water to finalize.

In March 2004, the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) (the Agencies) jointly released a document entitled "What You Need to Know About Mercury in Fish and Shellfish" (the 2004 advice). In June 2014, FDA and EPA announced a draft update that contains both advice and supplemental questions and answers for those who want to understand the advice in greater detail. Currently the FDA and EPA are seeking public comment on both the substance of the advice and how best to frame the advice for consumers so that it is both understandable and influential. Please review the draft updated advice and information presented in the Federal Register Notice (FR Doc. 2014-13584) and provide advice to the EPA Administrator with a focus on the following questions:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Also, we had some other questions:

1. Have you reached out to CHPAC members yet to ask who wants to be on the workgroup? And would the workgroup do any work prior to the meeting or would they get an assignment following the meeting? We have not reached out to CHPAC members yet to ask about interest in a fish advisory workgroup. We would like to do that this week. There will be at least one other workgroup for members to choose to join. The charge would go out to members when we ask for interest in the workgroup. The new workgroup would meet after the plenary CHPAC meeting on 9/10 to begin discussing a response to the charge.

2. Once the report is provided to the Administrator, does she review and then comment on it? Did you say that report would be submitted by the Administrator to the docket for seafood advice? A comment (advice) letter will be submitted to the Administrator. The agency generally responds to the letter. You can view the comment letter history on the CHPAC website (link above). The comment letter could also be submitted to the docket.

3. Would the committee and/or the workgroup examine the question posed in the FR notice in terms of what new studies would be needed going forward to provide future advice or based on the currently available studies what does the committee think of the proposed advice? The comment letter from the committee would focus on the latter as outline in the second charge question.

We realize the meeting is less than a month away and so we want to be able to get back to you as soon as possible. If you would find it easier for us to have a call to discuss the questions above, we would be pleased to arrange that.

Many thanks.

Sharon Natanblut

Director, Strategic Communications and Public Engagement

FDA Foods and Veterinary Medicine Directorate

From: Reed, Khesha [mailto:Reed.Khesha@epa.gov]
Sent: Wednesday, August 06, 2014 5:43 PM
To: Natanblut, Sharon
Subject: Children's Health Protection Advisory Committee

Sharon,

After discussing the outreach plan with EPA senior managers, we would like to engage the Children's Health Protection Advisory Committee (CHPAC) on the draft advice "Fish: What Pregnant Women and Parents Should Know". The CHPAC is a body of external researchers, academicians, health care providers, environmentalists, state and tribal government employees, and members of the public who advise EPA on regulations, research, and communications related to children's health. Members serve voluntarily and the CHPAC meets about two or three times per year to provide specific recommendations to the EPA administrator.

We believe that the third supplemental question posed in the FR noticed is ideally suited for the CHPAC's mission and expertise.

(3) Information upon which to base advice on young children's fish consumption. There have been a number of studies that have examined the effects of both postnatal exposure to mercury as well as postnatal fish consumption by young children, but this research has not been as extensive as the research on prenatal exposures and maternal fish consumption.

We believe the CHPAC would provide valuable feedback and propose directing the CHPAC to respond to this charge during the current comment period. The next CHPAC meeting is scheduled for September 9th and 10th. We could form a workgroup that can begin to draft a response at this meeting. Alternatively, the CHPAC could join the FDA Advisory Committee

on Risk Communication to jointly provide advice to the EPA Administrator and FDA Commissioner on both risk communications and fish consumption.

We are currently drafting the agenda for the September meeting and welcome your feedback as we determine if it should include the fish advisory now or table the topic for a joint meeting.

Feel free to contact me if you have questions or concerns.

Thank you,

Khesha Reed

Acting Director

Office of Children's Health Protection

(202) 566-0594

To: Barash, Shari[Barash.Shari@epa.gov]
From: Wathen, John
Sent: Fri 9/18/2015 2:42:51 PM
Subject: Fw: Briefing for FDA-EPA fish advice on 9/22 with DA
FISH_CHART_V_9.2.pdf
FISH_CHART_H_9.2.pdf
FDA-EPA Fish Advice briefing for DA.pptx

meant to cc you Shari

~John

From: Wathen, John
Sent: Friday, September 18, 2015 10:41 AM
To: Schoeny, Rita
Cc: Hisel-Mccoy, Sara; Larimer, Lisa
Subject: Fw: Briefing for FDA-EPA fish advice on 9/22 with DA

I'm glad I had these handy, Rita.

~John

From: Larimer, Lisa
Sent: Wednesday, September 16, 2015 3:41 PM
To: Wathen, John
Subject: FW: Briefing for FDA-EPA fish advice on 9/22 with DA

From: Larimer, Lisa
Sent: Wednesday, September 16, 2015 2:31 PM
To: Conerly, Octavia
Cc: Hisel-Mccoy, Sara
Subject: Briefing for FDA-EPA fish advice on 9/22 with DA

Octavia-

Sara has reviewed the briefing. I am also including the files for the horizontal and vertical versions of the charts – they are easier to read than in the briefing. I believe Betsy only forwarded one version up to Ken for his briefing; you may want to check with her on that for this time.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Wed 9/16/2015 9:27:33 PM
Subject: Re: Briefing for FDA-EPA fish advice on 9/22 with DA

Tanks.

From: Larimer, Lisa
Sent: Wednesday, September 16, 2015 3:41 PM
To: Wathen, John
Subject: FW: Briefing for FDA-EPA fish advice on 9/22 with DA

From: Larimer, Lisa
Sent: Wednesday, September 16, 2015 2:31 PM
To: Conerly, Octavia
Cc: Hisel-Mccoy, Sara
Subject: Briefing for FDA-EPA fish advice on 9/22 with DA

Octavia-

Sara has reviewed the briefing. I am also including the files for the horizontal and vertical versions of the charts – they are easier to read than in the briefing. I believe Betsy only forwarded one version up to Ken for his briefing; you may want to check with her on that for this time.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Tue 9/15/2015 8:58:19 PM
Subject: FW: PLEASE PROVIDE INPUT: draft rollout plan for 2015 FDA-EPA Fish Consumption Advice
Fish Consumption Advice 2015_Roll Out_KH+CLjw9-15-15.docx

From: Wathen, John
Sent: Tuesday, September 15, 2015 3:47 PM
To: Larimer, Lisa; Fontenelle, Samantha
Subject: RE: PLEASE PROVIDE INPUT: draft rollout plan for 2015 FDA-EPA Fish Consumption Advice

I think this is ready to go to the next set of eyes and hands.

~John

From: Larimer, Lisa
Sent: Tuesday, September 15, 2015 2:38 PM
To: Lalley, Cara; Wathen, John; Fontenelle, Samantha
Cc: Christensen, Christina; McDonald, Ambria
Subject: RE: PLEASE PROVIDE INPUT: draft rollout plan for 2015 FDA-EPA Fish Consumption Advice

John, Samantha and I are working on the ones with EPA by them. We will send you something Thursday, possibly sooner.

From: Lalley, Cara
Sent: Tuesday, September 15, 2015 11:26 AM
To: Larimer, Lisa; Wathen, John; Fontenelle, Samantha
Cc: Christensen, Christina; McDonald, Ambria
Subject: RE: PLEASE PROVIDE INPUT: draft rollout plan for 2015 FDA-EPA Fish

Consumption Advice

Yes- I will have Travis ask the FDA comms folks to make sure those answers are updated (or deleted or modified to reflect the final fish advice)—you can also feel free to share them with the technical folks you've been working with in the interim. Thanks

From: Larimer, Lisa
Sent: Tuesday, September 15, 2015 11:20 AM
To: Lalley, Cara; Wathen, John; Fontenelle, Samantha
Cc: Christensen, Christina; McDonald, Ambria
Subject: RE: PLEASE PROVIDE INPUT: draft rollout plan for 2015 FDA-EPA Fish Consumption Advice

Cara, I need some clarification. The Q&A have [FDA] or [EPA] or a combination next to them. Does that mean you've already worked out with FDA that they will update the ones with [FDA]?

From: Lalley, Cara
Sent: Monday, September 14, 2015 5:44 PM
To: Wathen, John; Fontenelle, Samantha; Larimer, Lisa
Cc: Christensen, Christina; McDonald, Ambria
Subject: PLEASE PROVIDE INPUT: draft rollout plan for 2015 FDA-EPA Fish Consumption Advice
Importance: High

Please review this draft rollout plan. In particular, please add in the "anticipated reactions" of your various stakeholder groups by COB this Wed. Please respond to the other comments/questions and update the "EPA" Q&A by COB this Friday.

Travis will review and share this draft with relevant comm folks here in EPA and the team he's begun working with at FDA.

We'd like to have a joint rollout plan for the final advice instead of just a joint set of key

messages and Q&A as we did in 2014. There will be many details to keep track of in planning for October between the two agencies.

Thanks,

Cara Lalley

Communications Coordinator

Office of Science & Technology

U.S. EPA Office of Water

(202)566-0372 (p)

(202)566-1140 (f)

From: Wathen, John
Location: by phone
Importance: Normal
Subject: Accepted: Discuss requested edits to fish advice
Start Date/Time: Wed 8/12/2015 2:00:00 PM
End Date/Time: Wed 8/12/2015 3:00:00 PM

To: Jones, William[William.Jones@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Wathen, John
Sent: Wed 8/5/2015 5:56:20 PM
Subject: RE: Let me know when's a good time to call you

One thing I would mention, Bill, is that Holly indicated she was working from the draft advice and not our latest and best.

~John

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Wednesday, August 05, 2015 1:53 PM
To: Larimer, Lisa
Cc: Wathen, John; Natanblut, Sharon; Smegal, Deborah
Subject: RE: Let me know when's a good time to call you

Our Center Director has contacted our Chief Counsel directly to see if we can do this yet…waiting to hear back. I was just drafting a response Holly letting her know this in so many word, while looping you in so you would see our response. I will send that now, then will forward to Debbie, Sharon and John so we're all on the same page.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, August 05, 2015 1:40 PM
To: Jones, William; Smegal, Deborah
Cc: Wathen, John; Natanblut, Sharon
Subject: FW: Let me know when's a good time to call you

In case Sharon is indisposed…. Ideally we'd like to call HHS back tomorrow morning.

From: Larimer, Lisa
Sent: Wednesday, August 05, 2015 12:54 PM
To: Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)
Subject: Let me know when's a good time to call you

John and I left you a VM. Bottom line is our mgmt got a call from Holly McPhee in HHS about our joint fish advice and the dietary guidelines. We wanted to talk to you before we called her back.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Wed 8/5/2015 5:32:20 PM
Subject: RE: Thoughts on invitees to Admin briefing on fish advice?

One or two of the OCP folks- Michael Firestone and Keish Reed (optional)?

From: Larimer, Lisa
Sent: Wednesday, August 05, 2015 12:56 PM
To: Wathen, John
Subject: Thoughts on invitees to Admin briefing on fish advice?

Typing up the request got bumped back to me. Everyone and their brother is asking to be invited (e.g., OSP, communications). Who am I missing? Are there folks I should push back on and not invite? Here's who I have so far:

EPA Staff (Required):	Lisa Larimer, John Wathen, Sara Hisel-McCoy, Elizabeth Southerland, Ken Kopocis, Thomas Burke
EPA Staff (Optional):	Jeff Bigler, Travis Loop, Cara Lalley, Robert Kavlock, Fred Hauchman, Rita Schoeny

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Wathen, John
Sent: Thur 8/25/2016 8:27:46 PM
Subject: RE: Summary of Reference provided in the Public comments

That's great, Debbie. You have definitely got the resources!

~John

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, August 25, 2016 4:01 PM
To: Jones, William <William.Jones@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Li, Cissy <Cissy.Li@fda.hhs.gov>; Flannery, Brenna <Brenna.Flannery@fda.hhs.gov>; Kim, Grace <Grace.Kim@fda.hhs.gov>; Dennis, Sherri <Sherri.Dennis@fda.hhs.gov>
Subject: Summary of Reference provided in the Public comments

Hi,

My branch has carefully reviewed the references provided by the public commenters. This has been a major undertaking because in the 222 public comments, 467 unique references were cited. The references were screened for relevance, yielding 319 references that were categorized as shown in this table:

# References	Category
56	Mercury in fish and neurodevelopmental health endpoints
28	Mercury exposure from fish consumption
13	Mercury levels in fish
56	Mercury - other topics, non-neuro health endpoints
9	Other contaminants in fish
24	Fatty acids/omega 3's from fish
4	Other benefits of fish (selenium)
15	Risk-benefit analysis
26	Psychology of fish advice, perception, communication
15	Other groups' fish advice
39	From regulatory agencies (FDA, EPA, etc.)

11	Opinion and commentary
23	Miscellaneous
319	**TOTAL**

Attached in this email are two documents. First is a Word document that summarizes the

Ex. 5 - Deliberative Process

Second is an Excel spreadsheet that Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process The spreadsheet contains many tabs, which are described below:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Please review these documents for your own information, and to provide any feedback to us. We can do more work on this as needed. We can use this information as we continue to revise the fish advice, which we can discuss in a follow-up meeting.

Thanks to Cissy, Brenna, Grace, and Sheila for their hard work!

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Wed 8/24/2016 6:47:01 PM
Subject: RE: what I've pulled together
Preview summary of peer review commentsLLjw8-24-16.docx

Looks good- I added a few items. I am going to read the comments through again and may have more of it in my head later or in the morning.

~John

From: Larimer, Lisa
Sent: Wednesday, August 24, 2016 1:29 PM
To: Wathen, John <Wathen.John@epa.gov>
Subject: what I've pulled together

I essentially did the contractors' work for them, but we know that people won't be willing to wait for their report. . .

From: Wathen, John
Location: DCRoomARN3530CFTB/DC-Ariel-Rios-AO
Importance: Normal
Subject: Accepted: FDA-EPA Fish Advice
Start Date/Time: Tue 9/22/2015 3:00:00 PM
End Date/Time: Tue 9/22/2015 3:45:00 PM

From: Wathen, John
Location: DCRoomARN3530CFTB/DC-Ariel-Rios-AO
Importance: Normal
Subject: Accepted: FDA-EPA Fish Advice
Start Date/Time: Thur 9/17/2015 9:00:00 PM
End Date/Time: Thur 9/17/2015 9:45:00 PM

To: Barash, Shari[Barash.Shari@epa.gov]
From: Wathen, John
Sent: Fri 8/28/2015 6:19:41 PM
Subject: Re: General Ruminations

Yes I thinkit turned out well too and I'm not unhappy about it. As you suggest, we will hopefully get more efficient with time. At our best, Denise and I would either write and the other edit, then the writer check. At the worst, Denise would write, I would check, then she would rewrite what she damn well please and had no one check. Sometimes that did not turn out well.

We have a different sit., because both of have technical sense, but everyone needs a check. The most important thing I learned in grad school was being good about taking editing. None of us is Earnest Hemingway, but even the best writers have editors.

~John

From: Barash, Shari
Sent: Friday, August 28, 2015 11:47 AM
To: Wathen, John
Cc: Larimer, Lisa
Subject: RE: General Ruminations

Thanks for the thoughts. I am totally open to feedback on how we can make it go smoothly and with less iterations (although I think the FL thing turned out well, so maybe it went ok). In general, I just think our managers need more translation of the scientific info so they get what the point is and the impact of their decisions.

Shari Z. Barash

Acting Chief

National Water Quality Standards Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Wathen, John
Sent: Friday, August 28, 2015 11:43 AM
To: Barash, Shari
Cc: Larimer, Lisa
Subject: General Ruminations

Did this send a minute ago? Anyway, I was saying that it is a pretty good dynamic when you can have three people covering something. I was reminded on the FL document that we all have some getting used to each other's working, communicating, writing, and editing styles to do. Lisa and I have been working very well on the Joint Advice with quick back and forth to each other on changes- (I think we are both introverts and you, Shari- not so much!)

Another thing I am aware of is that my writing is generally on things in the scientific realm and that I am less than fully facile in the language of quasi regulatorese. So I have some work to do to improve my utility to the new organization in this line of business.

Thank goodness my next major task is one that I am only about 6 months behind on thanks to my acting stint and other tasks. I have the NRSA organics paper to write with JIm Lazorchak, Angela Batt, and Tony Olsen. Angela is the lead author on this, but I have a good solid month of work to do on it before the end of the year. Good luck says I .

Have a good weekend

~John

From: Barash, Shari
Sent: Friday, August 28, 2015 11:25 AM

To: Wathen, John; Conerly, Octavia; Bethel, Heidi
Cc: Larimer, Lisa
Subject: RE: Meeting request materials for fish advice

I will be in except for 9/4.

Shari Z. Barash

Acting Chief

National Water Quality Standards Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Wathen, John
Sent: Friday, August 28, 2015 11:24 AM
To: Conerly, Octavia; Bethel, Heidi
Cc: Barash, Shari; Larimer, Lisa
Subject: Re: Meeting request materials for fish advice

Octavia, Heidi-

I will be in the office Mon-Wed if you have any questions about this. After that, I will be out 9/3-9/9. I believe Lisa will be back in on 9/9.

~John

From: Larimer, Lisa
Sent: Friday, August 28, 2015 10:26 AM
To: Barash, Shari
Cc: Wathen, John
Subject: Fw: Meeting request materials for fish advice

Octavia, Heidi and Matt were all out of the office, but Heidi was checking email and sent the stuff to Crystal to process and forwarded to Lynn while Octavia is out. Making sure you two have the materials in case anything comes up. Will probably be offline for most of the rest of the day now. See you in September!

-Lisa

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 5:35 PM
To: Bethel, Heidi; Conerly, Octavia; Klasen, Matthew
Subject: Meeting request materials for fish advice

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process. Here are the meeting request and memo for the briefing for the Administrator.

FYI, I won't be in the office tomorrow through Labor Day. John will be in the office tomorrow morning, but then out until Sept. 10. Hopefully you won't have any questions. If you do and can't reach us, try Samantha Fontenelle.

Thanks!

Lisa

To: Zipf, Lynn[Zipf.Lynn@epa.gov]
From: Wathen, John
Sent: Fri 8/28/2015 12:26:44 PM
Subject: FW: Summary of call w/ HHS & USDA on fish advice & dietary guidelines

From: Larimer, Lisa
Sent: Wednesday, August 26, 2015 1:05 PM
To: Hisel-Mccoy, Sara
Cc: Barash, Shari; Wathen, John
Subject: Summary of call w/ HHS & USDA on fish advice & dietary guidelines

Sara-

On Wednesday, Lisa and John and their FDA counterparts on the fish advice had a call with HHS and USDA on the 2015 Dietary Guidelines. Ex. 5 - Deliberative Process so they will submit the Administrator meeting request unless you have concerns.

Status of 2015 Dietary Guidelines

- In development stage. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

- HHS hopes to start clearance process in mid-September and **release by end of December 2015**.

Feedback on fish advice

Ex. 5 - Deliberative Process

Moving forward

- HHS will keep FDA & EPA in the loop as they develop the DGA content.

- Both groups (fish advice and DGA) felt it is important that Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process Both groups will keep each other informed re: exact timing.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Thur 8/27/2015 6:34:05 PM
Subject: Thoughts

Ex. 5 - Deliberative Process

~John

From: Larimer, Lisa
Sent: Thursday, August 27, 2015 12:42 PM
To: Deborah Smegal (Deborah.smegal@fda.hhs.gov); Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov); Bill Jones (William.jones@fda.hhs.gov); Wathen, John
Subject: Summary of call with HHS & USDA on fish advice

If it's useful, here are my notes from the call yesterday. I captured a few things for us to keep in mind as we go along.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Barash, Shari[Barash.Shari@epa.gov]
From: Wathen, John
Sent: Thur 8/27/2015 3:46:29 PM
Subject: RE: Summary of call w/ HHS & USDA on fish advice & dietary guidelines

Nice concise summary, Lisa.

~John

From: Larimer, Lisa
Sent: Wednesday, August 26, 2015 1:05 PM
To: Hisel-Mccoy, Sara
Cc: Barash, Shari; Wathen, John
Subject: Summary of call w/ HHS & USDA on fish advice & dietary guidelines

Sara-

On Wednesday, Lisa and John and their FDA counterparts on the fish advice had a call with HHS and USDA on the 2015 Dietary Guidelines. **Ex. 5 - Deliberative Process** so they will submit the Administrator meeting request unless you have concerns.

Status of 2015 Dietary Guidelines

- In development stage. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

- HHS hopes to start clearance process in mid-September and **release by end of December 2015**.

Feedback on fish advice

Ex. 5 - Deliberative Process

•□□□□□□□ Ex. 5 - Deliberative Process

Moving forward

•□□□□□□□ HHS will keep FDA & EPA in the loop as they develop the DGA content.

•□□□□□□□ Both groups (fish advice and DGA) felt Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process Both groups will keep each other informed re: exact timing.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Barash, Shari[Barash.Shari@epa.gov]
From: Wathen, John
Sent: Fri 8/21/2015 1:06:28 PM
Subject: Fw: Blurb for Friday AA meeting

Shari-

Here's what Lisa pulled together yest. Fully up to date. finalized documents entered into HHS process late yesterday.

By the way Shari, if I may, you did way too much work on the FL document summary. I do bullets- just say, let's bulletize.

~John

From: Larimer, Lisa
Sent: Thursday, August 20, 2015 2:22 PM
To: Frey, Sharon
Cc: Wathen, John
Subject: Blurb for Friday AA meeting

EPA-FDA fish advice

•□□□□□□ The materials (chart, Q&As, response to comments, etc.) have finally cleared FDA and are entering HHS' clearance process today (Friday).

•□□□□□□ We are holding off submitting the meeting request to brief the Administrator until we and FDA meet with the HHS and USDA group that is revising the Dietary Guidelines for Americans. We want to make sure there are no issues. We are meeting with them next week (Tues. or Wed.). We envision 3 possible outcomes:

Ex. 5 - Deliberative Process

•□□□□□□ After we know which direction the DGA group is leaning, which should be next week

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Thur 8/20/2015 5:55:57 PM
Subject: RE: Draft note for Friday AA meeting

Couple of suggested changes.

~John

From: Larimer, Lisa
Sent: Thursday, August 20, 2015 1:49 PM
To: Wathen, John
Subject: Draft note for Friday AA meeting

John - Did I capture this correctly? I didn't take notes, but I noticed you did.

EPA-FDA fish advice

•□□□□□□□ The materials (chart, Q&As, response to comments, etc.) have finally cleared FDA and are entering HHS' clearance process today (Friday).

•□□□□□□□ We are holding off submitting the meeting request to brief the Administrator until we and FDA meet with the HHS and USDA group that is revising the Dietary Guidelines for Americans. Ex. 5 - Deliberative Process We are meeting with them next week (Tues. or Wed.). We envision 3 possible outcomes:

Ex. 5 - Deliberative Process

•□□□□□□□ After we know which direction the DGA group is leaning, which should be next week – they have not seen any materials since the June 2014 draft advice Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process - we will schedule the Administrator's briefing.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Jones, William[William.Jones@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Wathen, John
Sent: Wed 8/12/2015 2:27:44 PM
Subject: RE: Discuss requested edits to fish advice Bills Block
How FDA and EPA derived the categories jw8-12.docx

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Wednesday, August 12, 2015 10:25 AM
To: Larimer, Lisa; Wathen, John; Bigler, Jeff; Smegal, Deborah; Natanblut, Sharon
Subject: RE: Discuss requested edits to fish advice

A significant edit to the FR notice to discuss:

IV. What comments were received and how does the revised fish advice reflect them?

Ex. 5 - Deliberative Process

-----Original Appointment-----
From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, August 06, 2015 1:59 PM
To: Larimer, Lisa; Wathen, John; Bigler, Jeff; Smegal, Deborah; Natanblut, Sharon; Jones, William
Subject: Discuss requested edits to fish advice
When: Wednesday, August 12, 2015 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: by phone

855-564-1700

Conference code

Participant code

Ex. 6 - Personal Privacy

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]
From: Wathen, John
Sent: Wed 8/12/2015 2:22:31 PM
Subject: FW: My edits to Bills block

My rewrite of Bill's block.

From: Wathen, John
Sent: Wednesday, August 12, 2015 8:20 AM
To: Larimer, Lisa; Fontenelle, Samantha; Bigler, Jeff
Subject: My edits to Bills block

Ex. 5 - Deliberative Process

~John

John Wathen, Acting Chief

Fish, Shellfish, Beaches, & Outreach Branch (4305 T)

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Standards and Health Protection Division

Office of Science and Technology

Office of Water

US Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, DC 20460

202-566-0367 phone

202-566-0409 fax

http://www.epa.gov/waterscience

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Wathen, John
Sent: Tue 8/11/2015 5:57:20 PM
Subject: FW: getting organized to brief Tom Burke on fish advice

Lisa-

I am pulling together a response to Rita. I have a pretty good chronology from my files and email unless you have maintained something better.

~John

From: Schoeny, Rita
Sent: Tuesday, August 11, 2015 1:30 PM
To: Wathen, John; Larimer, Lisa; Fontenelle, Samantha; Bigler, Jeff
Cc: Cantilli, Robert
Subject: getting organized to brief Tom Burke on fish advice

Hi, all. Putting together some material for Tom B in advance of any meeting with Gina. I plan to steal the PPT you used with Ken as well as the fish advice, Q and A etc.

But for background, can you tell me in a couple of sentences what happened with the advice between summer 2012 (when I have my last notes) and now. I recall that we and FDA sent draft advice with Q and A to HHS; I remember that we got EPA sign off on a draft FR, etc. And then I thought that the advice disappeared into the vastness of HHS. And then . . . (I know Tom B will ask about any post 2012 FACA as well as the public comments).

RSVP. I would like to get goodies over to Tom in a day or two. Thanks.

Rita Schoeny, Ph.D.
Senior Science Advisor, Office of Science Policy
Office of Research and Development

U.S. Environmental Protection Agency
Room 51134 RRB
1200 Pennsylvania Avenue NW (8104R)
Washington DC 20460-0001

202-566-1127
202-565-2911 fax

Address for delivery:
1300 Pennsylvania Ave. NW
Room# 51134 MC8104R
Washington DC 20004

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Tue 9/27/2016 5:50:35 PM
Subject: RE: Using shared documents

My understanding was that the 9.26 version started our meeting yesterday and that the accepted edits constituted a new document. I believe my bullets at the top of page 4 of the undated version that we accepted yesterday were those last edits in that previous version.

~John

From: Larimer, Lisa
Sent: Tuesday, September 27, 2016 1:27 PM
To: Wathen, John <Wathen.John@epa.gov>
Subject: RE: Using shared documents

Thanks, John. Did you also modify the one without a date yesterday? It's showing that you were the last one to modify it.

From: Wathen, John
Sent: Tuesday, September 27, 2016 1:04 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Deborah Smegal (Deborah.smegal@fda.hhs.gov) <Deborah.smegal@fda.hhs.gov>; Bill Jones (William.jones@fda.hhs.gov) <William.jones@fda.hhs.gov>; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov) <Sharon.Natanblut@fda.hhs.gov>
Subject: RE: Using shared documents

I'll consolidate my changes into the version from after the meeting yesterday. They are limited.

It is done. The version labeled Peer Review Response fish advice 9.26.16 is the operative version. There were no other changes than mine to the JWlate version which I have deleted.

My bad.

~John

From: Larimer, Lisa
Sent: Tuesday, September 27, 2016 12:38 PM
To: Deborah Smegal (Deborah.smegal@fda.hhs.gov) <Deborah.smegal@fda.hhs.gov>; Wathen, John <Wathen.John@epa.gov>; Bill Jones (William.jones@fda.hhs.gov) <William.jones@fda.hhs.gov>; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov) <Sharon.Natanblut@fda.hhs.gov>
Subject: Using shared documents

Hi everyone,

The whole point behind putting our documents in a shared folder was so we would have one version of each document that everyone was working from. Please do **not** save the file with a different name! This creates a separate file, and then everyone else doesn't know which one they should be editing. If you are worried about being able to track changes over time, don't be. There's a version history capability – it saves a copy every time the document has been saved.

We now have 3 versions of the peer review response document in the folder, all of which have been changed after we met yesterday. Someone is going to have to reconcile all those. The odds of me having time to do it is virtually nil, and my team is overextended as it is. Do any of you have an available staff person who is handy with Word that could download all 3 versions, combine all changes into one document, and upload it? If you do, let me know the email address so I can grant access.

Thanks,

Lisa

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Deborah Smegal (Deborah.smegal@fda.hhs.gov)[Deborah.smegal@fda.hhs.gov]; Bill Jones (William.jones@fda.hhs.gov)[William.jones@fda.hhs.gov]; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov)[Sharon.Natanblut@fda.hhs.gov]
From: Wathen, John
Sent: Tue 9/27/2016 5:03:34 PM
Subject: RE: Using shared documents

I'll consolidate my changes into the version from after the meeting yesterday. They are limited.

It is done. The version labeled Peer Review Response fish advice 9.26.16 is the operative version. There were no other changes than mine to the JWlate version which I have deleted.

My bad.

~John

From: Larimer, Lisa
Sent: Tuesday, September 27, 2016 12:38 PM
To: Deborah Smegal (Deborah.smegal@fda.hhs.gov) <Deborah.smegal@fda.hhs.gov>; Wathen, John <Wathen.John@epa.gov>; Bill Jones (William.jones@fda.hhs.gov) <William.jones@fda.hhs.gov>; Sharon' 'Natanblut (Sharon.Natanblut@fda.hhs.gov) <Sharon.Natanblut@fda.hhs.gov>
Subject: Using shared documents

Hi everyone,

The whole point behind putting our documents in a shared folder was so we would have one version of each document that everyone was working from. Please do **not** save the file with a different name! This creates a separate file, and then everyone else doesn't know which one they should be editing. If you are worried about being able to track changes over time, don't be. There's a version history capability – it saves a copy every time the document has been saved.

We now have 3 versions of the peer review response document in the folder, all of which have been changed after we met yesterday. Someone is going to have to reconcile all those. The odds of me having time to do it is virtually nil, and my team is overextended as it is. Do any of you have an available staff person who is handy with Word that could download all 3 versions, combine all changes into one document, and upload it? If you do, let me know the email address so I can grant access.

Thanks,

Lisa

From: Wathen, John
Location: DCRoomWest6105AAssateague/DC-EPA-West-OST
Importance: Normal
Subject: Accepted: 5th EPA-FDA meeting on fish advice
Start Date/Time: Thur 6/11/2015 1:00:00 PM
End Date/Time: Thur 6/11/2015 8:00:00 PM

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Jones, William[William.Jones@fda.hhs.gov]; Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Elkin, Ted[Ted.Elkin@fda.hhs.gov]
From: Wathen, John
Sent: Mon 5/11/2015 10:56:29 PM
Subject: Re: 4th FDA-EPA meeting on fish advice

I always schedule time for lunch...

~John

From: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Sent: Monday, May 11, 2015 6:15 PM
To: Larimer, Lisa; Bigler, Jeff; Jones, William; Smegal, Deborah; Elkin, Ted; Wathen, John
Subject: RE: 4th FDA-EPA meeting on fish advice

Hi there,

Turns out I have an HHS conference call between 12 and 12:30 on Wednesday. Would you mind if we scheduled that time for lunch?
Thanks.
Sharon

-----Original Appointment-----
From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Thursday, April 16, 2015 10:45 AM
To: Larimer, Lisa; Bigler, Jeff; Jones, William; Smegal, Deborah; Natanblut, Sharon; Elkin, Ted; Wathen, John
Subject: 4th FDA-EPA meeting on fish advice
When: Wednesday, May 13, 2015 9:00 AM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: CFSAN CP Room 2E-032

Main topic: Tackle the response to comments

From: Wathen, John
Location: 3233 WJCE
Importance: Normal
Subject: FW: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy
Start Date/Time: Mon 8/3/2015 5:00:00 PM
End Date/Time: Mon 8/3/2015 5:30:00 PM
Joint FDA_EPA Fish Advice_07_13_2015.pdf
FDA-EPA Fish Advice briefing.pptx
Briefing agenda.doc
draft FR notice-fish advice.Version 1.docx
FISH_CHART_H_7.24.pdf

We need to get poor Albert off of this...

-----Original Appointment-----
From: Kopocis, Ken
Sent: Monday, July 13, 2015 12:02 PM
To: Kopocis, Ken; Southerland, Elizabeth; Hisel-Mccoy, Sara; Larimer, Lisa; Bigler, Jeff; Wathen, John
Cc: Naidenko, Olga; Fontenelle, Albert; Conerly, Octavia; Gilinsky, Ellen; Penman, Crystal; Fontenelle, Samantha
Subject: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy
When: Monday, August 03, 2015 1:00 PM-1:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: 3233 WJCE

Poc Lisa Larimer 202-566-1017

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Mon 8/3/2015 1:16:52 PM
Subject: RE: FDA-EPA fish advice files

Gotcha-

The remote Outlook has snagged me more than once.

~John

From: Larimer, Lisa
Sent: Sunday, August 02, 2015 11:59 AM
To: Wathen, John; Schroer, Lee
Subject: Re: FDA-EPA fish advice files

John,

Those were attached as well. You had to scroll down to see all the attachments.

-Lisa

From: Wathen, John
Sent: Friday, July 31, 2015 4:49 PM
To: Larimer, Lisa; Schroer, Lee
Subject: Re: FDA-EPA fish advice files

Lisa, Lee-

Should Lee cast his perspicacious eyes on our response to comments document as well?

~John

From: Larimer, Lisa
Sent: Friday, July 31, 2015 2:48 PM
To: Schroer, Lee
Cc: Wathen, John
Subject: FDA-EPA fish advice files

Hi Lee,

Shari said she talked to you and that you were willing to look over our materials related to the updated FDA-EPA fish advice. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

We are briefing Ken on Monday afternoon. It would be great if you could look these over by then, but not expected since we didn't send them until Friday afternoon. If Ken asks, we can always say that OGC is in the process of reviewing them.

Thanks! And have a great weekend,

Lisa

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Thur 7/30/2015 1:41:14 PM
Subject: FW: Will Reschedule: RE: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy

Bummer!

From: Bethel, Heidi **On Behalf Of** Kopocis, Ken
Sent: Thursday, July 30, 2015 8:29 AM
To: Kopocis, Ken; Southerland, Elizabeth; Hisel-Mccoy, Sara; Larimer, Lisa; Bigler, Jeff; Wathen, John
Cc: Naidenko, Olga; Fontenelle, Albert; Conerly, Octavia; Gilinsky, Ellen; Penman, Crystal; Fontenelle, Samantha; Edwards, Crystal; Penman, Crystal
Subject: Will Reschedule: RE: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code 234567
Importance: High

Good Morning,
I just wanted to let you know that this meeting will be rescheduled, most likely for next week. Crystal P is out today. If it doesn't come off the calendar before 2 pm, please know that it will be moved.
Thanks,
Heidi
(202) 566-2054

-----Original Appointment-----
From: Penman, Crystal **On Behalf Of** Kopocis, Ken
Sent: Monday, July 13, 2015 12:02 PM
To: Kopocis, Ken; Southerland, Elizabeth; Hisel-Mccoy, Sara; Larimer, Lisa; Bigler, Jeff; Wathen, John
Cc: Naidenko, Olga; Fontenelle, Albert; Conerly, Octavia; Gilinsky, Ellen; Penman, Crystal; Fontenelle, Samantha
Subject: Joint FDA/EPA Fish Advise call in 855-564-1700 ext Ex. 6 - Personal Privacy participant code Ex. 6 - Personal Privacy
When: Thursday, July 30, 2015 2:00 PM-2:45 PM (UTC-05:00) Eastern Time (US & Canada).
Where: 3233 WJCE

Poc Lisa Larimer 202-566-1017

<< File: Joint FDA_EPA Fish Advice_07_13_2015.pdf >> << File: FDA-EPA Fish Advice briefing.pptx >> << File: Briefing agenda.doc >> << File: draft FR notice-fish advice.Version 1.docx >> << File: FISH_CHART_H_7.24.pdf >>

From: Wathen, John
Location: 1-855-564-1700 conference extension: 1104465 participant code 234567
Importance: Normal
Subject: Accepted: Discuss proposed edits to fish advice materials
Start Date/Time: Fri 7/31/2015 6:00:00 PM
End Date/Time: Fri 7/31/2015 7:00:00 PM

From: Wathen, John
Location: DCRoomWest1144C/OCHP
Importance: Normal
Subject: Accepted: update on FDA-EPA fish advice
Start Date/Time: Wed 7/29/2015 5:00:00 PM
End Date/Time: Wed 7/29/2015 6:00:00 PM

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Tue 7/28/2015 3:04:23 PM
Subject: RE: Requesting an informal meeting on FDA-EPA updated fish advice

Nice…

~John

From: Larimer, Lisa
Sent: Tuesday, July 28, 2015 10:58 AM
To: Berger, Martha
Cc: Wathen, John
Subject: Requesting an informal meeting on FDA-EPA updated fish advice

Martha,

We in the Office of Science and Technology would love to update you on what the final version of the FDA-EPA fish advice is looking like and how CHPAC's recommendations were addressed. In an ideal world, we'd like to meet with Ruth Etzel and whichever staff are interested in this project before we brief our AA on Thursday afternoon. Whatever magic you can work on your end would be much appreciated.

Here are some relevant files in case people want to take a look before the meeting.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Tue 7/28/2015 1:58:05 PM
Subject: Rita's
Fish Advice Qs and As-070915 - schoenyjw07 27 15.docx

My eds on Rita's comments.

~John

John Wathen, Acting Chief

Fish, Shellfish, Beaches, & Outreach Branch (4305 T)

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Standards and Health Protection Division

Office of Science and Technology

Office of Water

US Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, DC 20460

202-566-0367 phone

202-566-0409 fax

http://www.epa.gov/waterscience

To: Hisel-Mccoy, Sara[Hisel-McCoy.Sara@epa.gov]; Evelyn Washington[Washington.Evelyn@epa.gov]; Barash, Shari[Barash.Shari@epa.gov]; Buffo, Corey[Buffo.Corey@epa.gov]; Keating, Jim[Keating.Jim@epa.gov]
Cc: Larimer, Lisa[Larimer.Lisa@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Wathen, John
Sent: Wed 5/6/2015 11:44:09 AM
Subject: FDA item for BS Bi-weekly

FDA Fish Advice update-chart color selection for optimal communication

~John

John Wathen, Acting Chief

Fish, Shellfish, Beaches, & Outreach Branch (4305 T)

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Standards and Health Protection Division

Office of Science and Technology

Office of Water

US Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, DC 20460

202-566-0367 phone

202-566-0409 fax

http://www.epa.gov/waterscience

To: Robiou, Grace[Robiou.Grace@epa.gov]
From: Wathen, John
Sent: Mon 4/20/2015 4:58:29 PM
Subject: RE: URGENT - Antyhing for the week in review email? FDA meeting? Im still very much catching up. eom

I sent Sara an item to that effect, but she didn't think it need to be elevated.

~John

From: Robiou, Grace
Sent: Monday, April 20, 2015 12:55 PM
To: Hisel-Mccoy, Sara; Washington, Evelyn; Buffo, Corey; Barash, Shari; Wathen, John
Subject: RE: URGENT - Antyhing for the week in review email? FDA meeting? Im still very much catching up. eom

John, should we include an item on the Fish Advice – 2nd mtg with FDA Last week?

From: Hisel-Mccoy, Sara
Sent: Monday, April 20, 2015 11:30 AM
To: Robiou, Grace; Washington, Evelyn; Buffo, Corey; Barash, Shari; Wathen, John
Subject: URGENT - Antyhing for the week in review email? FDA meeting? Im still very much catching up. eom

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Wathen, John
Sent: Fri 4/17/2015 7:35:58 PM
Subject: Input on progress draft, couple of Qs andAs
draft advice from Sharon-revised at 041415 mtgjw4-17-15.docx

My input du jour. We'll hammer through these next week.

~John

Cc: Bigler, Jeff[Bigler.Jeff@epa.gov]; Robiou, Grace[Robiou.Grace@epa.gov]
To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Fri 4/17/2015 4:09:42 PM
Subject: Re: Materials resulting from Second FDA-EPA Meeting on Fish Advice

I found it. I had deleted after "use this one" email.

~John

From: Larimer, Lisa
Sent: Tuesday, April 14, 2015 4:57 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: Materials resulting from Second FDA-EPA Meeting on Fish Advice

Here are the chart and the revised advice/Q&As.

-----Original Appointment-----
From: Robiou, Grace
Sent: Tuesday, March 17, 2015 3:31 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Larimer, Lisa; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: Second FDA-EPA Meeting on Fish Advice
When: Tuesday, April 14, 2015 9:00 AM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest6105AAssateague/DC-EPA-West-OST

Cc: Bigler, Jeff[Bigler.Jeff@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]
To: Robiou, Grace[Robiou.Grace@epa.gov]
From: Wathen, John
Sent: Fri 4/17/2015 3:33:51 PM
Subject: Fw: Update on revised FDA-EPA fish advice

Grace-

Did Lisa send/share/ otherwise transmit the progress draft of the the advice to you? If so, please provide.

~John

From: Larimer, Lisa
Sent: Wednesday, April 15, 2015 1:20 PM
To: Southerland, Elizabeth
Cc: Robiou, Grace; Wathen, John; Hisel-Mccoy, Sara
Subject: Update on revised FDA-EPA fish advice

Hi Betsy,

Since Sara is out, I thought I'd give you a quick update on the fish Ex. 5 - Deliberative Process advice. We had a productive face-to-face meeting yesterday, in which the joint group agreed on many issues, including:

Ex. 5 - Deliberative Process

We have another face-to-face meeting scheduled next Wednesday to hammer out the revised Q&As before we lose a bunch of people to travel for a while. In mid-May we will meet again to focus on the response to comments. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

I don't want to overpromise, but we may have **Ex. 5 - Deliberative Process** for management review in May if things continue to go smoothly.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

Cc: Bigler, Jeff[Bigler.Jeff@epa.gov]
To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Fri 4/17/2015 3:30:55 PM
Subject: Re: Summary of 4/14 FDA-EAP meeting on fish advice

Lisa-

Do you have a copy of the progress draft of the advice text?

~John

From: Larimer, Lisa
Sent: Wednesday, April 15, 2015 4:40 PM
To: Smegal, Deborah; Carrington, Clark D; Jones, William; Robiou, Grace; Wathen, John; Bigler, Jeff; Ted.Elkin@fda.hhs.gov
Subject: Summary of 4/14 FDA-EAP meeting on fish advice

Hi everyone,

Just thought I'd capture some of the more substantive things we agreed to at our 4/14 meeting while it's still fresh:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Coming within a few days: Draft mock-ups of the chart from Sharon

Please let me know if I left anything off or mischaracterized anything.

Thanks!

Lisa Larimer, P.E.

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: John Wathen[Wathen.John@epa.gov]
From: Wathen, John
Sent: Thur 4/16/2015 8:03:21 PM
Subject: FW: Second FDA-EPA Meeting on Fish Advice
Agenda-Fish Advice-041415 FDA-EPA mtg.docx
Handout 2 Fish advice chart-041315.xlsx
Handout 5 Annotated QA-040715.docx
Handout 6 Table of Synthesized Comments-040715.docx
Handout 1 Summary of All Public Comments on Advice-040715.docx

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From: Larimer, Lisa
Sent: Monday, April 13, 2015 1:05 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: RE: Second FDA-EPA Meeting on Fish Advice

Hi everyone. Here is the agenda and handouts 1, 2, 5 and 6 for tomorrow's meeting.
[Sharon, if you bring or send the electronic file with the projected mark-ups to the advice, I can project it on the big screen.]

Logistics:
Enter through the EPA West entrance at 1301 Constitution Ave, NW (same one as before) - Federal Triangle metro stop.
Call John Wathen at 202-566-0367 to lead you up.
Meeting will be in 6105A.
Call-in number is 855-564-1700; conference extension = Ex. 6 - Personal Privacy; participant code = Ex. 6 - Personal Privacy

We look forward to seeing you! We have a jam-packed agenda.

Lisa Larimer, P.E.
U.S. Environmental Protection Agency | Washington, DC
Office of Water | Standards and Health Protection Division
☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

-----Original Appointment-----
From: Robiou, Grace
Sent: Tuesday, March 17, 2015 3:31 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Larimer, Lisa; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: Second FDA-EPA Meeting on Fish Advice
When: Tuesday, April 14, 2015 9:00 AM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest6105AAssateague/DC-EPA-West-OST

From: Wathen, John
Location: TBD
Importance: Normal
Subject: Accepted: HOLD: 4th FDA-EPA meeting on fish advice
Start Date/Time: Wed 5/13/2015 1:00:00 PM
End Date/Time: Wed 5/13/2015 8:00:00 PM

From: Wathen, John
Location: FDA - College Park campus
Importance: Normal
Subject: Accepted: 3rd FDA-EPA meeting on fish advice
Start Date/Time: Wed 4/22/2015 12:30:00 PM
End Date/Time: Wed 4/22/2015 4:30:00 PM

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Robiou, Grace[Robiou.Grace@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Naidenko, Olga[Naidenko.Olga@epa.gov]; Carrington, Clark D[Clark.Carrington@fda.hhs.gov]; 'Natanblut, Sharon'[Sharon.Natanblut@fda.hhs.gov]; 'William.jones@fda.hhs.gov'['William.jones@fda.hhs.gov']; 'Deborah.smegal@fda.hhs.gov'['Deborah.smegal@fda.hhs.gov']; 'Elkin, Ted'[Ted.Elkin@fda.hhs.gov]
From: Wathen, John
Sent: Tue 4/14/2015 11:57:58 AM
Subject: RE: Second FDA-EPA Meeting on Fish Advice

FDA colleagues-

Let's see who's on their smart phones this AM. Given the pretty steady rain, it may benefit overall dryness for you to come in through the indoor route. When you come up the Federal Triangle escalator, turn left and you are facing the entrance of William J Clinton South (WJCS).

You can enter the complex there, sign in there, and I can come meet you there (202-566-0367). For anyone driving, you can still come to the Constitution Ave entrance, but if I am picking folks up at WJCS, I won't be at my desk, so here is my cell- Ex. 6 - Personal Privacy

I look forward to our meeting today.

~John

From: Larimer, Lisa
Sent: Monday, April 13, 2015 1:05 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: RE: Second FDA-EPA Meeting on Fish Advice

Hi everyone. Here is the agenda and handouts 1, 2, 5 and 6 for tomorrow's meeting.
[Sharon, if you bring or send the electronic file with the projected mark-ups to the advice, I can project it on the big screen.]

Logistics:
Enter through the EPA West entrance at 1301 Constitution Ave, NW (same one as before) - Federal Triangle metro stop.
Call John Wathen at 202-566-0367 to lead you up.
Meeting will be in 6105A.
Call-in number is 855-564-1700; conference extension = Ex. 6 - Personal Privacy; participant code = Ex. 6 - Personal Privacy

We look forward to seeing you! We have a jam-packed agenda.
<< File: Agenda-Fish Advice-041415 FDA-EPA mtg.docx >> << File: Handout 1 Summary of All Public Comments on Advice-040715.docx >> << File: Handout 2 Fish advice chart-041315.xlsx >> << File: Handout 5 Annotated QA-040715.docx >> << File: Handout 6 Table of Synthesized Comments-040715.docx >>
Lisa Larimer, P.E.
U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division
☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

-----Original Appointment-----
From: Robiou, Grace
Sent: Tuesday, March 17, 2015 3:31 PM
To: Robiou, Grace; Bigler, Jeff; Naidenko, Olga; Wathen, John; Larimer, Lisa; Carrington, Clark D; 'Natanblut, Sharon'; 'William.jones@fda.hhs.gov'; 'Deborah.smegal@fda.hhs.gov'; 'Elkin, Ted'
Subject: Second FDA-EPA Meeting on Fish Advice
When: Tuesday, April 14, 2015 9:00 AM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomWest6105AAssateague/DC-EPA-West-OST

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Wathen, John
Sent: Tue 11/10/2015 1:01:32 PM
Subject: RE: Do you know over what time period OMB had the fish advice for review?

Haven't the foggiest.

~John

From: Larimer, Lisa
Sent: Sunday, November 08, 2015 11:43 PM
To: Wathen, John <Wathen.John@epa.gov>; Bigler, Jeff <Bigler.Jeff@epa.gov>
Subject: Do you know over what time period OMB had the fish advice for review?

I'm pulling together a timeline and have been asked to include the OMB review, but I have no clue when that was. Can either of you dig that up? I'll probably need it before Monday afternoon.

Thanks!

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Mon 11/2/2015 2:14:07 PM
Subject: FW: Advice2

Ex. 5 - Deliberative Process

FISH_CHART_15-10-15.pdf

From: John Wathen [mailto:jwath(Ex. 6 - Personal Privacy
Sent: Sunday, November 01, 2015 9:31 AM
To: jwath(Ex. 6 - Personal Privacy Wathen, John <Wathen.John@epa.gov>
Subject: Advice2

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Wathen, John
Sent: Fri 10/23/2015 1:21:36 PM
Subject: RE: EPA OIG investigation on contaminants in seafood

Betsy-

I am here today if you want to discuss.

~John

From: Larimer, Lisa
Sent: Thursday, October 22, 2015 1:56 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: EPA OIG investigation on contaminants in seafood

I'm calling Sharon now.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, October 22, 2015 1:26 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: FW: EPA OIG investigation on contaminants in seafood

Hi there,

Just heard about this and was hoping we could find a time to discuss.

Thanks.

Sharon

From: Natanblut, Sharon
Sent: Thursday, October 22, 2015 1:25 PM
To: Sharp, Jeremy; Kux, Leslie
Cc: Boon, Caitlin; McKinnon, Robin; Cristinzio, Dayle; Pillsbury, Laura; Saben, Alyson L; Bernard, Susan; Mayne, Susan; Harper, Kristina; Taylor, Michael R
Subject: RE: EPA OIG investigation on contaminants in seafood

FYI

From: Sonya Lunder [mailto:sonya@ewg.org]
Sent: Thursday, October 22, 2015 12:09 PM
To: Natanblut, Sharon
Subject: EPA OIG investigation on contaminants in seafood

Sharon,

Here is the EPA OIG notice about its investigation into contaminant warnings by EPA's Office of Water. As I also mentioned today, EWG is planning to formally ask EPA and FDA to hold of on finalizing the draft seafood advice while this investigation is pending. We believe the draft advice is not health protective, as detailed in our public comments to FDA. We have provided OIG with model advice from state governments that is more comprehensive and nuanced, as a model for the federal agencies to employ when advising pregnant women and parents.

Thanks for forwarding this information to the scientists in charge of mercury issues. I would be eager to speak with them about the Agency's plans to incorporate public comments and update the draft advice.

- Sonya

Sonya Lunder, MPH

Environmental Working Group

Washington DC 20009

Sonya@ewg.org

202/939-9129

To: Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Wathen, John
Sent: Mon 7/27/2015 6:44:05 PM
Subject: RE: FSBOB Notes for 7/27

I knew that. Don't know why Tom Popped out.

~John

From: Bigler, Jeff
Sent: Monday, July 27, 2015 2:31 PM
To: Wathen, John
Cc: Larimer, Lisa
Subject: Re: FSBOB Notes for 7/27

By the way - it's "Ted" Coopwood...

□□□□□

On Jul 24, 2015, at 11:08 AM, Wathen, John <Wathen.John@epa.gov> wrote:

Evelyn-

FSBOB Notes.

~John

FSBOB Notes for OD Staff Meeting 7/27/15

FDA/EPA Joint Fish Advice

The OST Ex. 5 - Deliberative Process team met with Bob Cantilli and Cindy Roberts in OSP-ORD on Wednesday 7/22 to provide them with the Joint Advice documents and context around the process of its release. We agreed that Rita Schoeny would be an appropriate individual to look at the materials ahead of Fred Hauchman. They also advised that if it is to go to the Administrator, Tom Burke in ORD Ex. 5 - Deliberative Process

The team has a meeting scheduled with Tom Coopwood in OCHP to initiate a similar process.

Beach Program

The Form 5170 for the 2016 Beach Conference remains has been transmitted to the Administrator's office for final approval. SHPD is monitoring its progress.

OST has been invited to the initial meeting for the audit of the Beach Program with OIG on August 12.

Fish Tissue Contaminant Studies

Beth Murphy at GLNPO has put out a call for assistance on Great Lakes sample collection for the NCCA and has had positive feedback for USGS, NYDEC, MI & WI. No specifics are available, but it looks like we will be getting meaningful help from cooperating agencies.

Fish Advisory Program

The WA for the peer review of the FCS doc is now in the hands of contracts. We expect the package to be processed with the contractor within the next 1-2 weeks. That would keep us on the overall FCS doc schedule provided earlier.

Ex. 5 - Deliberative Process

To: Bigler, Jeff[Bigler.Jeff@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Barash, Shari[Barash.Shari@epa.gov]
From: Wathen, John
Sent: Mon 7/27/2015 4:13:02 PM
Subject: FW: Files associated with updated FDA-EPA fish advice

Meant to cc yall.

~John

From: Wathen, John
Sent: Monday, July 27, 2015 12:10 PM
To: Cantilli, Robert; Larimer, Lisa
Cc: Schoeny, Rita
Subject: RE: Files associated with updated FDA-EPA fish advice

Thanks Bob, and thanks Rita. We covered some ground, eh?

~John

From: Cantilli, Robert
Sent: Monday, July 27, 2015 11:47 AM
To: Wathen, John; Larimer, Lisa
Subject: FW: Files associated with updated FDA-EPA fish advice

You're good to go from ORD's point of view.

From: Schoeny, Rita
Sent: Thursday, July 23, 2015 2:53 PM
To: Cantilli, Robert; Roberts, Cindy
Cc: Fegley, Robert
Subject: RE: Files associated with updated FDA-EPA fish advice

Please let the OW folks know that I am completely and totally thrilled with the Advice, Q and A, etc., and that I will help in any way to get this out the door. Of course, I have a couple suggested edits and comments. I know, however, that pretty much every word of this has been negotiated to death; so we ought not be insistent on any of my quibbles.

What a treat to see this!

From: Cantilli, Robert
Sent: Wednesday, July 22, 2015 2:08 PM
To: Schoeny, Rita
Subject: FW: Files associated with updated FDA-EPA fish advice

Rita: Please let me know if anything jumps out at you on this. I did a quick review and it looks pretty good to me but I haven't been involved with this like you have. Let's shoot for Tuesday COB.

From: Larimer, Lisa
Sent: Wednesday, July 22, 2015 1:13 PM
To: Roberts, Cindy; Cantilli, Robert
Cc: Wathen, John
Subject: Files associated with updated FDA-EPA fish advice

Cindy and Bob,

Here are the files for the fish advice: the charts, Qs & As, response to comments document and text for the technical web page.

FYI, the email John sent out earlier today went to my personal email, so please don't use that one.

Lisa Larimer, P.E. | **Team Leader**

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Wathen, John
Location: TBD
Importance: Normal
Subject: Accepted: FDA-EPA fish advice update
Start Date/Time: Tue 7/28/2015 2:00:00 PM
End Date/Time: Tue 7/28/2015 3:00:00 PM

To: Larimer, Lisa[Larimer.Lisa@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Wathen, John
Sent: Fri 7/17/2015 7:07:27 PM
Subject: Re: Communications for fish advice

I would suggest that what Cara is very appropriately referring to is part of the next phase of activity- the big outreach.

~John

From: Larimer, Lisa
Sent: Friday, July 17, 2015 3:04 PM
To: Wathen, John; Bigler, Jeff
Subject: FYI: Communications for fish advice

From: Lalley, Cara
Sent: Friday, July 17, 2015 1:11 PM
To: Larimer, Lisa
Subject: Re: Communications for fish advice

Hey Lisa,

I think I have a joint comm plan and key messages/Q&A in the office. Will send it to you next week.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Of course, the use of Web and social media is much more widespread today than 2004, so that will be a new consideration this time around as well. I have to guess that contractors have plenty of data on multilingual usage of these media (or lack thereof) over the past several years.

I mentioned all this stuff at OST staff meeting a few weeks ago, so Evelyn, Sara and Betsy are aware.

What is your best guess as to FDA's timing for public release of the final advice?

Thanks

From: Larimer, Lisa
Sent: Friday, July 17, 2015 12:03 PM
To: Lalley, Cara
Subject: Communications for fish advice

Hi Cara,

We need to start planning our communications roll-out for the fish advice. Although FDA will probably be playing a large part in the external communications, I know we need to show our plan. Do you have the communication strategy for the draft 2014 fish advice? I'm hoping I can borrow heavily from that.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Wathen, John
Location: DCRoomWest6105ERockCreek/DC-EPA-West-OST
Importance: Normal
Subject: Accepted: Prep for meeting w/ FDA on fish advice
Start Date/Time: Tue 6/23/2015 7:00:00 PM
End Date/Time: Tue 6/23/2015 7:30:00 PM

From: Wathen, John
Location: DCRoomWest6105AAssateague/DC-EPA-West-OST
Importance: Normal
Subject: New Time Proposed: response to comments-fish advice
Start Date/Time: Tue 5/19/2015 6:30:00 PM
End Date/Time: Tue 5/19/2015 8:30:00 PM

I don't think I can afford 2 hrs today. I need the 2-3 block for the Beach Program.

~John

To: Lalley, Cara[Lalley.Cara@epa.gov]
Cc: Larimer, Lisa[Larimer.Lisa@epa.gov]; Evelyn Washington[Washington.Evelyn@epa.gov]
From: Wathen, John
Sent: Mon 2/23/2015 4:14:30 PM
Subject: RE: fish advice comms for comment period closing

Cara-

The attachments are OK.

~John

From: Lalley, Cara
Sent: Monday, February 23, 2015 9:51 AM
To: Wathen, John
Subject: FW: fish advice comms for comment period closing

Please see below and respond ASAP. Thanks

Sent from my Windows Phone

From: Brubaker, Sonia
Sent: 2/20/2015 3:27 PM
To: Lalley, Cara
Cc: Loop, Travis; Larimer, Lisa; Washington, Evelyn
Subject: FW: fish advice comms for comment period closing

Hi Cara,

We just received this - let us know if you'd like to provide feedback or comments. The FR notice will be published on Monday.

Copying in Lisa and Evelyn per your out of office note.

Thanks!

Sonia

Sonia Brubaker
Acting Deputy Director of Communications
Office of Water

U.S. Environmental Protection Agency

(202) 564-0120

brubaker.sonia@epa.gov

From: Daguillard, Robert
Sent: Friday, February 20, 2015 3:15 PM
To: Loop, Travis; Brubaker, Sonia
Cc: Hull, George
Subject: FW: fish advice comms for comment period closing

About the soon-to-close comment period on the joint FDA-EPA fish advice:

From FDA, a Friday afternoon heads-up – and request for feedback and/or comment - about a Federal Register notice going out Monday morning.

Maybe Betsy does have some feedback, although at this stage, I suppose I'm just forwarding it so everybody's on the same page.

From: Eisenman, Theresa [mailto:Theresa.Eisenman@fda.hhs.gov]
Sent: Friday, February 20, 2015 2:58 PM
To: Daguillard, Robert
Subject: FW: fish advice comms for comment period closing

From: Eisenman, Theresa
Sent: Friday, February 20, 2015 2:35 PM
To: 'hull.george@epa.gov'
Subject: fish advice comms for comment period closing

George, Per our phone conversation, please see attached documents. The KMQA (key message/ reactive Q&A) is to assist us in responding to questions. We don't publish the KMQA. We do publish the constituent update on our Web site. Please let me know if there are concerns. My direct number is **Ex. 6 - Personal Privacy**

To: Lalley, Cara[Lalley.Cara@epa.gov]
Cc: Hisel-Mccoy, Sara[Hisel-McCoy.Sara@epa.gov]; Robiou, Grace[Robiou.Grace@epa.gov]; Bigler, Jeff[Bigler.Jeff@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Evelyn Washington[Washington.Evelyn@epa.gov]
From: Wathen, John
Sent: Mon 2/23/2015 3:08:31 PM
Subject: RE: fish advice comms for comment period closing

Cara-

We are in business with FDA on this. This is the close of the comment period on our joint FDA-EPA draft revised mercury fish advisory. We will be reviewing the comments with FDA, preparing joint responses, and revising the draft advisory to reflect input from constructive commenters.

From: Lalley, Cara
Sent: Monday, February 23, 2015 9:51 AM
To: Wathen, John
Subject: FW: fish advice comms for comment period closing

Please see below and respond ASAP. Thanks

Sent from my Windows Phone

From: Brubaker, Sonia
Sent: 2/20/2015 3:27 PM
To: Lalley, Cara
Cc: Loop, Travis; Larimer, Lisa; Washington, Evelyn
Subject: FW: fish advice comms for comment period closing

Hi Cara,

We just received this - let us know if you'd like to provide feedback or comments. The FR notice will be published on Monday.

Copying in Lisa and Evelyn per your out of office note.

Thanks!

Sonia

Sonia Brubaker
Acting Deputy Director of Communications
Office of Water

U.S. Environmental Protection Agency

(202) 564-0120

brubaker.sonia@epa.gov

From: Daguillard, Robert
Sent: Friday, February 20, 2015 3:15 PM
To: Loop, Travis; Brubaker, Sonia
Cc: Hull, George
Subject: FW: fish advice comms for comment period closing

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From FDA, a Friday afternoon heads-up – and request for feedback and/or comment - about a Federal Register notice going out Monday morning.

Maybe Betsy does have some feedback, although at this stage, I suppose I'm just forwarding it so everybody's on the same page.

From: Eisenman, Theresa [mailto:Theresa.Eisenman@fda.hhs.gov]
Sent: Friday, February 20, 2015 2:58 PM
To: Daguillard, Robert
Subject: FW: fish advice comms for comment period closing

From: Eisenman, Theresa
Sent: Friday, February 20, 2015 2:35 PM
To: 'hull.george@epa.gov'
Subject: fish advice comms for comment period closing

George, Per our phone conversation, please see attached documents. The KMQA (key message/ reactive Q&A) is to assist us in responding to questions. We don't publish the KMQA. We do publish the constituent update on our Web site. Please let me know if there are concerns. My direct number is **Ex. 6 - Personal Privacy**

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
Cc: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Thur 7/28/2016 6:55:32 PM
Subject: On another matter

Sharon-

Any word on the signing of the MOU?

~John

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Thursday, July 28, 2016 2:37 PM
To: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: Fish advice peer review

What would be our next option and would it delay things?

From: Smegal, Deborah
Sent: Thursday, July 28, 2016 2:36 PM
To: Jones, William; Natanblut, Sharon; Larimer, Lisa; Wathen, John
Subject: RE: Fish advice peer review

Ex. 5 - Deliberative Process

Lisa and Sharon what do you think?

Debbie

From: Wathen, John <Wathen.John@epa.gov>
Date: July 28, 2016 at 2:11:25 PM EDT
To: Larimer, Lisa <Larimer.Lisa@epa.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>, Jones, William <William.Jones@fda.hhs.gov>
Subject: RE: Fish advice peer review

Thank you, Bill.

Ex. 5 - Deliberative Process

Here is a link to where the organization (Maine CDC) stands on this topic.

http://www.maine.gov/dhhs/mecdc/environmental-health/eohp/fish/documents/meffguide.pdf

~John

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Thursday, July 28, 2016 2:01 PM
To: Wathen, John <Wathen.John@epa.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: Fish advice peer review

I am comfortable getting on board with John's thoughts on this.

From: Wathen, John [mailto:Wathen.John@epa.gov]
Sent: Thursday, July 28, 2016 1:13 PM
To: Smegal, Deborah; Jones, William; Natanblut, Sharon; Larimer, Lisa
Subject: RE: Fish advice peer review

Ex. 5 - Deliberative Process

~John

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, July 28, 2016 12:03 PM
To: Jones, William <William.Jones@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: FW: Fish advice peer review

HI,

What do you think? I need to let them know ASAP.

DEbbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Cowen, Tracey [mailto:TCowen@versar.com]
Sent: Thursday, July 28, 2016 11:13 AM
To: Papadakis, Lori; Smegal, Deborah
Cc: Bottimore, David
Subject: Fish advice peer review

Hi Lori and Debbie,

Ex. 5 - Deliberative Process

Thanks,

Tracey

Tracey L. Cowen

Environmental Scientist

Environmental Services Group

Office: 301-304-3121

Email: tcowen@versar.com

Visit us at: www.versar.com

From: Wathen, John
Location: wiley building--room 2A-023
Importance: Normal
Subject: Accepted: fish advice peer review discussion--in person
Start Date/Time: Mon 9/26/2016 1:00:00 PM
End Date/Time: Mon 9/26/2016 4:00:00 PM

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Wathen, John
Sent: Mon 6/20/2016 6:15:32 PM
Subject: RE: Final Seafood Advice

That's great, Betsy. He'll get an earful from those folks.

~John

From: Southerland, Elizabeth
Sent: Monday, June 20, 2016 2:01 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: Final Seafood Advice

Sure thing! I am going to a meeting now with Tom Burke and EWG on mercury in fish. Sadly EWG did a whole report focused on trying to get EPA and FDA to specify which fish should be limited or not in terms of consumption. **Ex. 5 - Deliberative Process**

From: Beauvais, Joel
Sent: Monday, June 20, 2016 1:53 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: RE: Final Seafood Advice

Thanks, Betsy. You guys ok if I pass this email forward to Tom B and Kacee to engage them on this?

From: Southerland, Elizabeth

Sent: Monday, June 20, 2016 1:51 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Final Seafood Advice

We reviewed the revised draft charge from FDA (and corresponding email from Jeremy) and compared it to the version we sent to them in January (both versions are attached).

Overall we do not have any issues with FDA's changes to the charge to the peer reviewers.

For your information, we found the following changes:

Ex. 5 - Deliberative Process

Begin forwarded message:

From: "Beauvais, Joel" <Beauvais.Joel@epa.gov>
Date: June 17, 2016 at 12:33:14 PM EDT
To: "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Cc: "Campbell, Ann" <Campbell.Ann@epa.gov>
Subject: FW: Final Seafood Advice

Hi, Betsy – Can I get your input on this in advance of engaging with Tom B?

Joel

From: Sharp, Jeremy [mailto:Jeremy.Sharp@fda.hhs.gov]
Sent: Friday, June 17, 2016 12:09 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Subject: Final Seafood Advice

Joel, I apologize for the long delay in my engagement of you on this. In our in-person meeting about EPA's concerns and proposed changes to the FDA-EPA fish advice, you outlined 3 general areas of concern. We are most anxious to move forward to finalize the advice, and in the time since our meeting have worked to address and respond to your requests as noted below.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process We look forward to hearing from you as soon as possible.

Jeremy Sharp

Deputy Commissioner

Policy, Planning, Legislation, and Analysis

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, Maryland 20993

301-796-8770

To: Barash, Shari[Barash.Shari@epa.gov]
From: Wathen, John
Sent: Mon 6/20/2016 3:00:17 PM
Subject: RE: Draft charge questions for peer review of FDA-EPA fish advice

Turns out I did have the 1/11 EPA version. I had just gotten rusty on my file structure.

Tough being me.

~John

From: Barash, Shari
Sent: Monday, June 20, 2016 8:24 AM
To: Wathen, John <Wathen.John@epa.gov>
Cc: Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: FW: Draft charge questions for peer review of FDA-EPA fish advice

John,

I see that you responded to Betsy. Sorry, I forgot to copy you when I sent this. If you look at it and have thoughts, just send to Lisa and I. I want Lisa to be able to be the one to submit to Betsy this morning.

Thanks,

Shari

Shari Z. Barash

Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Barash, Shari
Sent: Monday, June 20, 2016 8:16 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Lisa Larimer <Larimer.Lisa@epa.gov>; Sara Hisel-McCoy <Hisel-McCoy.Sara@epa.gov>
Subject: FW: Draft charge questions for peer review of FDA-EPA fish advice

Just wanted all of us to have the draft charge questions we sent to FDA in hand. We will do a comparison and write up a note for Betsy to send Joel first thing this morning.

Shari Z. Barash

Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Southerland, Elizabeth
Sent: Tuesday, January 12, 2016 4:32 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Cc: Bethel, Heidi <Bethel.Heidi@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>;

Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Draft charge questions for peer review of FDA-EPA fish advice

Jeremy-

Ex. 5 - Deliberative Process

To: Wathen, John[Wathen.John@epa.gov]; jwath@ **Ex. 6 - Personal Privacy**
From: Wathen, John
Sent: Sun 10/18/2015 2:48:39 PM
Subject: W/APPCPs
Historical Context Points for Ken Kopocis AppCPs.docx

Yep

Historic context of the 2015 FDA-EPA Fish Advice

for Ken Kopocis 10/23/15

FDA first issued consumption advice relating to methylmercury in **1994.**

In **January 2001**, the FDA issued a mercury advisory on the hazard posed by fish purchased in stores and restaurants. It advised pregnant women and women who could become pregnant to avoid eating shark, swordfish, king mackerel and tilefish, but suggested they could safely cook and eat 12 ounces per week of a variety of other kinds of fish.

Also in **January 2001**, EPA issued a fish advisory for mercury in fresh waters, advising young children and women who were pregnant, who could become pregnant, or who were nursing a baby to limit consumption of freshwater fish caught by family and friends to one six-ounce meal per week.

Amid general concerns over inconsistent federal fish advisories, and complaints from environmental groups that the FDA's guidelines were not protective enough, the FDA's Food Advisory Committee (FAC) was convened by the FDA's Center for Food Safety and Applied Nutrition (CFSAN) in **July 2002**.

FDA CMO David Acheson **2003** mandate: "bring commercial and recreational fish under the same umbrella advisory.

2003 discussion points:

Case Discussion Questions

1) What populations should the fish advisory target?
2) What obstacles must be overcome to develop effective fish advisories?
3) Where should the RfD be set at and what are the considerations for setting it?
4) What should the FDA/EPA's recommendations be with respect to the amount and type of fish that should be consumed by the American public?
5) What should the FDA/EPA's recommendations be regarding the consumption of tuna by the American public?
6) What should the FDA/EPA's recommendations be regarding the consumption of fish by children?
7) How should the advisory be communicated to the public?

In **2004** EPA and FDA issued joint advice.

Attachment A "Advice for: Women Who Might Become Pregnant, Women Who Are Pregnant, Nursing Mothers, Young Children"

June 2005- FDA-EPA MOU facilitates greater collaboration between FDA's Center for Food Safety and Applied Nutrition and EPA/OW on activities addressing the safety of fish consumption.

August 2008- EPA is considering options for future advice updates.

Attachment B: Case: Fish: Here's the Catch

In **late 2009**, EPA learned from OMB that FDA was preparing to release a draft document on the risk/benefit analysis (RBA); EPA was provided a few days to review the 450+ page document prior to release for public comment; FDA considered EPA's comments in developing a second draft of the

document for public release in April 2009, the analyses themselves were essentially unchanged, and in the opinion of EPA, scientifically flawed. EPA concluded in a 60 page response to public comments that the draft of the risk / benefit report released for public comment was not an appropriate basis for public policy decision.

February 2011-.Memorandum of Understanding on Environmental Contaminants in Fish and Shellfish between the U.S. Food and Drug Administration CFSAN and the U.S. EPA Office of Water was signed. Attachment C.

Since April 2009, FDA had been revising and EPA has been commenting on versions of the RBA. The most recent iteration came to EPA in **May 2011** behind, but in the same binder as a new proposed joint advice. That advice document included acceptable levels of consumption that exceeded the EPA-IRIS reference dose for methylmercury by many multiples for many species of fish.

In **October 2012**, EPA transmitted final comments to FDA on this RBA iteration, releasing FDA to pursue peer review but separating it from EPA's consideration in a revised joint advice document. Excerpts from RBA- Attachment D

In **September of 2013**, EPA and FDA representatives initiated discussion on a revised advice document. In November of 2014, a draft was agreed upon that closely resembled the 2004 advice.

In **April of 2014** Office of Children's Health Protection's Children's Health Protection Advisory Committee considered the draft revised advice.

In **June of 2014**, FDA and EPA released that draft for public comment. 240 comments received.
Attachment E: Draft Advice

November 2014 the draft advice was reviewed by FDA's *Risk Communication Advisory Committee (RCAC)*

December 23, 2014- Office of Children's Health Protection's Children's Health Protection Advisory Committee released its recommendations letter and Appendix on the draft revised advice. Attachment F.

In **March of 2015**, designated staff from FDA-CFSAN and EPA-OST began discussions on revisions to the draft advice.

Ex. 5 - Deliberative Process

October 15, 2015-FDA and EPA staff finalized agreement on Advice Chart, Qs and As, and Technical page, incorporating input from management in both agencies. Attachment H.

Attachment A "Advice for: Women Who Might Become Pregnant, Women Who Are Pregnant, Nursing Mothers, Young Children"

Attachment B:
Case: Fish: Here's the Catch

Attachment C:

February 2011 Memorandum of Understanding on Environmental Contaminants in Fish and Shellfish between the U.S. Food and Drug Administration CFSAN and the U.S. EPA Office of Water.

Attachment D:

Excerpts from RBA

Attachment E:

2014 Draft Advice

Attachment F:

Office of Children's Health Protection's Children's Health Protection Advisory Committee released its recommendations letter and Appendix on the draft revised advice.

Attachment G:

Ex. 5 - Deliberative Process

Attachment H:

FDA and EPA staff finalized agreement on Advice Chart, Qs and As, and Technical page, incorporating input from management in both agencies.

To: jwath@ Ex. 6 - Personal Privacy Wathen, John[Wathen.John@epa.gov]
From: Wathen, John
Sent: Sun 10/18/2015 2:26:42 PM
Subject: KKDocs 2
FDA Letter.pdf
Historical Context Points for Ken Kopocis 10.docx
Ex. 5 - Deliberative Process

Yep

To: jwath[redacted] Wathen, John[Wathen.John@epa.gov]
From: Wathen, John
Sent: Sun 10/18/2015 2:24:02 PM
Subject: KK docs
DGAC15EPAcomm4-8-15ES.pdf
FDA Letter.pdf
FISH CASE FINAL.pdf
MOU FDA-EPA drft clean agreed Jan 24.docx

From: Wathen, John
Location: 5233A WJC-W
Importance: Normal
Subject: FW: Next steps on FDA-EPA Fish Advisory
Start Date/Time: Wed 1/28/2015 2:00:00 PM
End Date/Time: Wed 1/28/2015 2:30:00 PM

-----Original Appointment-----
From: Hisel-Mccoy, Sara
Sent: Friday, January 23, 2015 3:49 PM
To: Hisel-Mccoy, Sara; Southerland, Elizabeth; Wathen, John; sharon.natanblut@fda.hhs.gov; ted.elkin@fda.hhs.gov
Cc: Skane, Elizabeth
Subject: Next steps on FDA-EPA Fish Advisory
When: Wednesday, January 28, 2015 9:00 AM-9:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: 5233A WJC-W

Ex. 6 - Personal Privacy

POC: John Wathen: 202 566 0367

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]
From: Wathen, John
Sent: Thur 10/15/2015 9:03:35 PM
Subject: RE: revised fish advice documents

Yep. 23 minute time lag. Good luck to us all.

~John

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Thursday, October 15, 2015 4:38 PM
To: Larimer, Lisa; Wathen, John
Cc: Natanblut, Sharon; Jones, William
Subject: FW: revised fish advice documents

Hi Lisa and John,

Here are the latest versions dated 10.15.15…..

Thanks for your input.

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

From: Smegal, Deborah
Sent: Thursday, October 15, 2015 4:36 PM
To: Natanblut, Sharon; Jones, William
Cc: Boon, Caitlin; Trumbo, Paula; McKinnon, Robin; Bernard, Susan; Elkin, Ted; Steadman, Marquita B
Subject: revised fish advice documents

Hi,

Attached please find all the latest documents to include:

(1) Response to HHS comments in a table format

(2) Qs and As with track changes

(3) Technical document with track changes

(4) Response to Public comment document with track changes

This incorporates input from EPA, and Paula,

I named all the files with 10.15.15 for version control.

I think Marquita has the cover memo that will accompany the responses.

Thanks for all your comments and input.

Regards,

Debbie

Deborah Smegal, MPH

Branch Chief, Contaminant Assessment Branch (CAB)

Division of Risk and Decision Analysis

Office of Analytics and Outreach

CFSAN, FDA

240-402-1818

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Thur 10/15/2015 6:07:58 PM
Subject: RE: Revised FISH_CHART-

Debbie-

Are you caught up with Lisa on responses or are you missing pieces still?

~John

From: Smegal, Deborah [mailto:Deborah.Smegal@fda.hhs.gov]
Sent: Wednesday, October 14, 2015 8:12 AM
To: Natanblut, Sharon; Jones, William; Larimer, Lisa; Wathen, John
Subject: RE: Revised FISH_CHART-

Hi Sharon,

Ex. 5 - Deliberative Process

Has this changed?

Regards,

Debbie

From: Natanblut, Sharon
Sent: Tuesday, October 13, 2015 6:41 PM
To: Smegal, Deborah; Jones, William; Larimer, Lisa; Wathen, John
Subject: Revised FISH_CHART-
Importance: High

Hi guys,

Here's the revised fish chart. Please see what you think of this approach. Once we have agreement on the direction, I'll have the designer spend a little more time on it to tighten it.

Sharon

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Barash, Shari[Barash.Shari@epa.gov]; Martinez, Menchu[martinez.menchu-c@epa.gov]
From: Wathen, John
Sent: Thur 10/8/2015 4:35:36 PM
Subject: RE: Update on FDA-EPA fish advice - input requested

Lisa-

I can't get option 1 to format properly. The lower boxes end up on a second page.

I am providing klutsie looking copies to Evelyn M., but you might need to work with her to get some better prints.

I am leaving the office in 2 mins.

~John

From: Larimer, Lisa
Sent: Thursday, October 08, 2015 11:02 AM
To: Deener, Kathleen
Cc: Southerland, Elizabeth; Hisel-Mccoy, Sara; Wathen, John
Subject: Update on FDA-EPA fish advice - input requested

Kacee-

Ex. 5 - Deliberative Process

The changes are :

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

From: Wathen, John
Location: DCRoomWest6105ERockCreek/DC-EPA-West-OST
Importance: Normal
Subject: Fish advice room
Start Date/Time: Wed 10/7/2015 4:30:00 PM
End Date/Time: Wed 10/7/2015 5:00:00 PM

From: Wathen, John
Location: Ex. 6 - Personal Privacy
Importance: Normal
Subject: Accepted: Fish advice check-in
Start Date/Time: Wed 10/7/2015 4:30:00 PM
End Date/Time: Wed 10/7/2015 5:00:00 PM

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Tue 10/6/2015 2:21:13 PM
Subject: FW: Quick update on FDA meeting on fish advice

Lisa-

Want to see it we can set something up with Ted Wed with revised advice in hand- maybe Ted and Ruth so we get the top on board?

~John

From: Hisel-Mccoy, Sara
Sent: Tuesday, October 06, 2015 7:41 AM
To: Barash, Shari
Cc: Larimer, Lisa; Wathen, John; Southerland, Elizabeth
Subject: Re: Quick update on FDA meeting on fish advice

Office of CHildrens health is on the invite for Thursday. John/Lisa I need you to connect with Ted who I believe is invited to the meeting and see if he's good with these changes. Then either you or I can connect with Ruth. **Ex. 5 - Deliberative Process** Ex. 5 - Deliberative Process with Stan. Let me know if we should discuss. Sara

Sara Hisel-McCoy

Standards and Health Protection Division

202 566-1649

On Oct 5, 2015, at 11:51 PM, Barash, Shari <Barash.Shari@epa.gov> wrote:

> Awesome work!
>
> Sent from my iPhone
>
> On Oct 5, 2015, at 11:40 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:
>
> > Sara-

I hear Ken will not be meeting with Stan until Thursday. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Fri 10/2/2015 7:54:46 PM
Subject: Re: Meeting with Stan Meiburg next week

Call it a half hour on the Metro from Archive. I think I'll plan to leave the office shortly before 9. I want to pick some stuff up and I could bring current documents for both of us.

~John

- **Rail Departs from**

  ARCHIVES METRO STATION

  at 8:05am

  Board

  GREEN LINE Rail
  towards GREENBELT

  Arrive

  COLLEGE PARK/U OF MD METRO STATION at 8:28am

There are active advisories that may affect your trip: View advisories

---

From: Larimer, Lisa
Sent: Friday, October 2, 2015 3:39 PM
To: Wathen, John
Subject: RE: Meeting with Stan Meiburg next week

I need to revisit how long the trip takes. Not sure if I'll stop by the office or go straight there

From: Wathen, John
Sent: Friday, October 02, 2015 1:42 PM
To: Larimer, Lisa
Subject: Re: Meeting with Stan Meiburg next week

Lisa-

I will be coming onto the office 1st thing Mon before I/we head up to CP.

~John

From: Larimer, Lisa
Sent: Friday, October 2, 2015 10:19:27 AM
To: Southerland, Elizabeth; Wathen, John; Barash, Shari; Hisel-Mccoy, Sara
Subject: RE: Meeting with Stan Meiburg next week

Will do! We'll be at FDA on Monday morning.

From: Southerland, Elizabeth
Sent: Friday, October 02, 2015 10:18 AM
To: Larimer, Lisa; Wathen, John; Barash, Shari; Hisel-Mccoy, Sara
Subject: Meeting with Stan Meiburg next week

Ken is setting up a meeting with Stan Meiburg early next week to discuss the Fish Advice issue. He was unable to get this scheduled for today.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Jones, William[William.Jones@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]
From: Wathen, John
Sent: Wed 9/30/2015 6:42:36 PM
Subject: RE: sign-offs on fish advice

Lisa and I could come out to CP Mon PM, but we are not sure we will have everything sorted out at this end by then. Shall we hold the time and see what happens with our internal meeting tomorrow?

~John

From: Jones, William [mailto:William.Jones@fda.hhs.gov]
Sent: Wednesday, September 30, 2015 2:11 PM
To: Larimer, Lisa
Cc: Smegal, Deborah; Wathen, John; Natanblut, Sharon
Subject: RE: sign-offs on fish advice

Working on this.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Wednesday, September 30, 2015 1:14 PM
To: Smegal, Deborah; Jones, William; Wathen, John; Natanblut, Sharon
Subject: sign-offs on fish advice

Can I get a list of who within HHS (including FDA I assume) has cleared the advice so far and what level/position they are? Would really like to have this before 10:30 tomorrow.

-Lisa

From: Wathen, John
Location: DCRoomWest5233B/DC-CCW-OST
Importance: Normal
Subject: Accepted: Next Steps on Fish Advice
Start Date/Time: Thur 10/1/2015 3:00:00 PM
End Date/Time: Thur 10/1/2015 4:00:00 PM

To: Lalley, Cara[Lalley.Cara@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]; Fontenelle, Samantha[Fontenelle.Samantha@epa.gov]; Barash, Shari[Barash.Shari@epa.gov]
From: Wathen, John
Sent: Fri 1/29/2016 7:44:08 PM
Subject: Re: Fish Tech Web Comments

Well, my guess is that if Sam was going to leave a voicemail, she did, thereby answering Lisa's question, subject to confirmation.

Thanks, Cara.

~John

From: Lalley, Cara
Sent: Friday, January 29, 2016 1:43 PM
To: Wathen, John; Larimer, Lisa; Fontenelle, Samantha; Barash, Shari
Subject: RE: Fish Tech Web Comments

No- this is not a press inquiry. The guy is a private environmental consultant who appears to own his own company. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

-----Original Message-----
From: Wathen, John
Sent: Friday, January 29, 2016 1:32 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>
Subject: Re: Fish Tech Web Comments

I thought it went up the OPA chain- Cara?

~John

From: Larimer, Lisa
Sent: Friday, January 29, 2016 12:19 PM
To: Wathen, John; Fontenelle, Samantha; Barash, Shari
Subject: RE: Fish Tech Web Comments

Did anyone ever call this guy?

-----Original Message-----
From: Wathen, John
Sent: Friday, January 08, 2016 3:48 PM
To: Fontenelle, Samantha <Fontenelle.Samantha@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Re: Fish Tech Web Comments

Ex. 5 - Deliberative Process Do we have a

current OPA person? Does one of us call with Travis on the line?

~John

From: Fontenelle, Samantha
Sent: Friday, January 8, 2016 3:43 PM
To: Barash, Shari; Larimer, Lisa; Wathen, John
Subject: FW: Fish Tech Web Comments

Passing along the phone number to the individual who asked the question about the status of the fish advice.

From: Stephen McCord
Sent: Friday, January 8, 2016 1:29:33 PM (UTC-05:00) Eastern Time (US & Canada)
To: Fish_Advisory
Subject: RE: Fish Tech Web Comments

Ph Ex. 6 - Personal Privacy

Stephen

-----Original Message-----
From: Fontenelle, Samantha [mailto:Fontenelle.Samantha@epa.gov] On Behalf Of Fish_Advisory
Sent: Friday, January 08, 2016 9:44 AM
To: Stephen McCord
Subject: Re: Fish Tech Web Comments

Greetings Mr. McCord,

We would like to follow up with you by phone regarding your inquiry. Could you please provide me with your phone number?

Respectfully,

CDR Samantha Fontenelle
US Public Health Service Commissioned Corps USEPA, Office of Water Washington, DC 20460 Room-5231X, MC-4305T
202-566-2083 (phone)
(202) 566-0409 (fax)

From: drupal_admin@epa.gov <drupal_admin@epa.gov> on behalf of Stephen McCord via EPA <drupal_admin@epa.gov>
Sent: Tuesday, January 5, 2016 1:54 PM
To: Fish_Advisory
Subject: Fish Tech Web Comments

Submitted on 01/05/2016 1:54PM
Submitted values are:

Name: Stephen McCord
Email: Ex. 6 - Personal Privacy
Comments: EPA and FDA issued updated draft advice on fish consumption in June 2014. Are there plans and a deadline for finalizing that advice?

To: Barash, Shari[Barash.Shari@epa.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Tue 1/12/2016 8:14:24 PM
Subject: FW: Dietary Guidelines/Fish Advice

For all our multiple input, I think the story about the advice comes across very well.

~John

From: Southerland, Elizabeth
Sent: Tuesday, January 12, 2016 12:05 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Bethel, Heidi <Bethel.Heidi@epa.gov>
Subject: RE: Dietary Guidelines/Fish Advice

We are waiting to hear back from KC Deener on the cover note for the fish advice. We want to make absolutely certain we are describing the peer review process accurately in that note. I will send the cover note with the attached charge questions as soon as I hear from her.

Ex. 5 - Deliberative Process

Let me know if you have any questions on this.

From: Beauvais, Joel
Sent: Monday, January 11, 2016 6:42 PM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Subject: Dietary Guidelines/Fish Advice

Hi – Can you give me an update when you get a chance on where things stand on Fish Advice peer review, etc., as well as your take o Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Daily News

Federal Dietary Guidelines Encourage Low-Mercury Fish Consumption

Posted: January 11, 2016

Newly released federal dietary guidelines encourage the public to increase its consumption of fish while also for the first time informing that fish species vary in the level of beneficial oils and harmful methylmercury they contain, picking up on draft advice EPA and the Food and Drug Administration (FDA) issued in 2014.

The finalized Dietary Guidelines for Americans (DGA), released Jan. 7, largely sidesteps the controversial advice an advisory panel gave to the Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA), where the advisors urged HHS and USDA to encourage EPA and FDA to reconsider their draft advice on tuna consumption. Tuna is one of the most commonly eaten fish in the U.S.

Instead, the DGA, which supersedes other federal guidance, repeats its 2010 advice, which for the first time set a floor for the amount of fish that Americans should eat on a weekly basis. The latest report reiterates that pregnant women, should eat no less than 8 ounces of fish per week, while not exceeding 12 ounces of fish per week.

New however, is the DGA's recognition that different seafood species contain different levels of methylmercury and varying amounts of beneficial oils. "For the general population, consumption of about 8 ounces per week of a variety of seafood, which provide an average consumption of 250 mg per day of [eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)], is associated with reduced cardiac deaths among individuals with and without preexisting [cardiovascular disease]," the DGA advises. "Similarly, consumption by women who are pregnant or breastfeeding of at least 8 ounces per week from seafood choices that are sources of DHA is associated with improved infant health outcomes."

The DGA continues by noting that "[w]omen who are pregnant or breastfeeding should consume at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in methylmercury. Obstetricians and pediatricians should provide guidance on how to make healthy food choices that include seafood. Women who are pregnant or breastfeeding and young children should not eat certain types of fish that are high in methylmercury."

The guidelines simplify the 2014 draft advisory from EPA and FDA that sought to balance EPA's traditional concerns that fish can be contaminated with methylmercury, a neurotoxin particularly potent to the developing fetus, with FDA's efforts to encourage women to eat more fish because the lean protein provides beneficial oils like Omega 3s and DHA that boost brain and eye development in the fetus.

The DGA, issued by HHS and USDA, is aimed at broadly advising all Americans on how to eat a healthy diet. It is also used to establish public school lunch menus and which foods are covered as part of federal consumer food subsidy programs.

Dietary Guidelines

Last year the Dietary Guidelines Advisory Committee (DGAC) suggested, based on FDA modeling, that EPA and FDA could increase the amount of albacore tuna that would be safe for these women to eat up to six ounces per week -- advice that horrified environmentalists and public health groups concerned with the amounts of mercury albacore tuna.

At a hearing last March, for example, William Wallace of Consumers Union urged the committee to recommend that EPA and FDA advise "that pregnant women eat no tuna." And in a June statement, several groups argued the DGAC's advice on consumption of albacore tuna would pose risks to children.

Tuna "is by far the largest source of mercury in the American diet, accounting for an estimated 45 percent of all mercury exposure," the groups said. "Albacore tuna has three times more mercury than light tuna and is therefore an unhealthy choice for pregnant women and children."

By contrast, the tuna industry at the March hearing reiterated the DGAC's advice, and some 29 senators in a letter to the FDA Commissioner Stephen Ostroff last April also encouraged reconsidering the albacore tuna limit, based on the DGAC's report.

The latest DGA does not list any species to avoid, as EPA and FDA do, but it does cite the general principles of those agencies' advice.

For the first time, the DGA lists specific types of seafood to recommend as high in beneficial oils and low in mercury -- not including any kind of tuna. "Seafood choices higher in EPA and DHA but lower in methylmercury are encouraged. Seafood varieties commonly consumed in the United States that are higher in EPA and DHA and lower in methylmercury include salmon, anchovies, herring, shad, sardines, Pacific oysters, trout, and Atlantic and Pacific mackerel (not king mackerel, which is high in methylmercury)."

A source with the Environmental Working Group cautiously praised the new advice. The DGA "gives some idea of the complexity to seafood advice, notably the best things [to eat] . . . it's a good list and it doesn't include tuna," the source says. "Some of it is so basic [what we've asked for and that] EPA and FDA avoided doing."

The source compared the DGA advice favorably to the 2014 draft advisory from EPA and FDA. "Compared to the EPA-FDA advice, this is an improvement," the source said. "It conveys some of the differences in the fish species. It gives a clear list [of recommended fish] and clear advice on numerical [limits]. But, the source adds, the advice is "weak on mercury," noting that it does not provide a list of fish to avoid.

The fishing industry is also touting the new DGA advice, though it also does not mention tuna. "When it comes to seafood the DGA's are clear -- seafood is called out over and over again as a food to encourage," a spokesman for the National Fisheries Institute says. "The DGA's do call for Americans to eat at least 8

[ounces] of fish per week to get the benefits but they also call on pregnant women to eat 8-12 ounces. This is significant because the FDA reports that currently pregnant women eat only 1.89 [ounces] a week, which means now they're missing out on the benefits of seafood." -- *Maria Hegstad* (mhegstad@iwpnews.com)

Related News | Mid Day E-mail | Toxics | Water |

187939

To: Barash, Shari[Barash.Shari@epa.gov]
From: Wathen, John
Sent: Tue 1/12/2016 4:44:08 PM
Subject: RE: Dietary Guidelines/Fish Advice

Betsy-

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Shari

Shari Z. Barash

Acting Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

From: Wathen, John
Sent: Tuesday, January 12, 2016 8:33 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Subject: RE: Dietary Guidelines/Fish Advice

Betsy-

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

~John

From: Southerland, Elizabeth
Sent: Monday, January 11, 2016 9:00 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Subject: Fwd: Dietary Guidelines/Fish Advice

What should we say regarding Joel's question?

Sent from my iPhone

Begin forwarded message:

> **From:** "Beauvais, Joel" <Beauvais.Joel@epa.gov>
> **Date:** January 11, 2016 at 6:42:21 PM EST
> **To:** "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>, "Hisel-Mccoy, Sara" <Hisel-McCoy.Sara@epa.gov>
> **Subject: Dietary Guidelines/Fish Advice**
>
> Hi – Can you give me an update when you get a chance on where things stand on Fish Advice peer review, etc., as well as your take [Ex. 5 - Deliberative Process]

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Daily News

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Instead, the DGA, which supersedes other federal guidance, repeats its 2010 advice, which for the first time set a floor for the amount of fish that Americans should eat on a weekly basis. The latest report reiterates that pregnant women, should eat no less than 8 ounces of fish per week, while not exceeding 12 ounces of fish per week.

New however, is the DGA's recognition that different seafood species contain different levels of methylmercury and varying amounts of beneficial oils. "For the general population, consumption of about 8 ounces per week of a variety of seafood, which provide an average consumption of 250 mg per day of [eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)], is associated with reduced cardiac deaths among individuals with and without preexisting [cardiovascular disease]," the DGA advises. "Similarly, consumption by women who are pregnant or breastfeeding of at least 8 ounces per week from seafood choices that are sources of DHA is associated with improved infant health outcomes."

The DGA continues by noting that "[w]omen who are pregnant or

breastfeeding should consume at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in methylmercury. Obstetricians and pediatricians should provide guidance on how to make healthy food choices that include seafood. Women who are pregnant or breastfeeding and young children should not eat certain types of fish that are high in methylmercury."

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At a hearing last March, for example, William Wallace of Consumers Union urged the committee to recommend that EPA and FDA advise "that pregnant women eat no tuna." And in a June statement, several groups argued the DGAC's advice on consumption of albacore tuna would pose risks to children.

Tuna "is by far the largest source of mercury in the American diet, accounting for an estimated 45 percent of all mercury exposure," the groups said. "Albacore tuna has three times more mercury than light tuna and is therefore an unhealthy choice for pregnant women and children."

By contrast, the tuna industry at the March hearing reiterated the DGAC's advice, and some 29 senators in a letter to the FDA Commissioner Stephen Ostroff last April also encouraged reconsidering the albacore tuna limit, based on the DGAC's report.

The latest DGA does not list any species to avoid, as EPA and FDA do, but it does cite the general principles of those agencies' advice.

For the first time, the DGA lists specific types of seafood to recommend as high in beneficial oils and low in mercury -- not including any kind of tuna. "Seafood choices higher in EPA and DHA but lower in methylmercury are encouraged. Seafood varieties commonly consumed in the United States that are higher in EPA and DHA and lower in methylmercury include salmon, anchovies, herring, shad, sardines, Pacific oysters, trout, and Atlantic and Pacific mackerel (not king mackerel, which is high in methylmercury)."

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Related News | Mid Day E-mail | Toxics | Water |

187939

To: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]
From: Wathen, John
Sent: Tue 9/29/2015 7:52:36 PM
Subject: NAS-IOM report 2006
11762[1].pdf

Debbie-

I actually was able to find the attached. I think it's a time of release copy.

~John

John Wathen

Senior Scientist, Fish and Beach Programs

National Standards Branch (4305 T)

<'}}}>< _/)~~~ <'}}}>< _/)~~~ <'}}}><

Standards and Health Protection Division

Office of Science and Technology

Office of Water

US Environmental Protection Agency

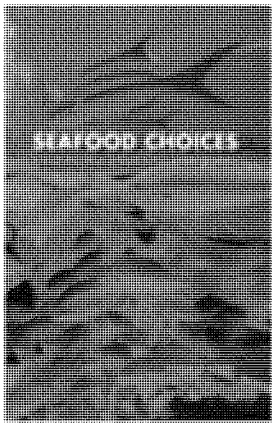
1200 Pennsylvania Ave NW

Washington, DC 20460

202-566-0367 phone

202-566-0409 fax

http://www.epa.gov/waterscience



Seafood Choices: Balancing Benefits and Risks

Committee on Nutrient Relationships in Seafood: Selections to Balance Benefits and Risks
ISBN: 0-309-66120-X, 736 pages, 6 x 9, (2007)
This PDF is available from the National Academies Press at: http://www.nap.edu/catalog/11762.html

Seafood Choices
Balancing Benefits and Risks

Committee on Nutrient Relationships in Seafood:
Selections to Balance Benefits and Risks
Food and Nutrition Board

Malden C. Nesheim and Ann L. Yaktine, *Editors*

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OF THE NATIONAL ACADEMIES

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COMMITTEE ON NUTRIENT RELATIONSHIPS IN SEAFOOD: SELECTIONS TO BALANCE BENEFITS AND RISKS

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Independent Report Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Johanna T. Dwyer**, Tufts University School of Medicine and Friedman School of Nutrition Science & Policy and Tufts–New England Medical Center and **Catherine E. Woteki**, Mars, Inc. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

Preface

When I was growing up, fish were considered "brain food." I was told that eating fish was good for you and would make you smart. Amazingly, there now is some evidence that this old food lore may have some scientific basis, as mothers who consume seafood may provide benefits to the developing fetal nervous system from fatty acids in the seafood. It is not clear, however, whether this will make you smarter as an adult.

Seafood is a good source of high-quality protein, is low in saturated fat, and is rich in many micronutrients. Seafood is also a major source of the long-chain polyunsaturated omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which are synthesized in limited amounts by the human body from alpha-linolenic acid (ALA), an omega-3 fatty acid found in several vegetable, nut, and seed oils. Though these fatty acids are found in other foods, some seafood is an unusually rich source. In the past several years, research has implicated seafood and/or EPA and DHA in an array of health benefits for the developing fetus, infants, and also for adults, especially those prone to heart disease. This has led to recommendations by several health authorities to include seafood in a healthy diet.

Seafood is the only animal protein food that is still provided in significant amounts to human diets through capture of wild species. Though our oceans are being depleted of some wild species, and aquaculture has become an important source of seafood, wild capture still provides a significant portion of the seafood we consume. The pollution of our oceans both through natural processes and practices of an increasingly industrialized world raise concern about the contaminants found in our seafood supply. As aquacul-

ture of some species also uses fish meal and fish oil produced from captured wild sources, farmed seafood is not free from potential risks of further reducing ocean stocks or from potential contaminants. As consumption of seafood rises, there has been an increasing awareness of the potential risks from seafood consumption due to the presence of microbial contaminants; persistent organic pollutants; and heavy metals, especially mercury, in our oceans and inland waters.

Consumers are therefore confronted with a dilemma: they are told that seafood is good for them and should be consumed in larger amounts than current consumption, while at the same time the federal government and virtually all the state governments have issued advisories urging caution in consumption of fish of certain species or from specific waters. Clearly, it should be an environmental priority to eliminate the sources of contamination of this important component of our food supply so that such a contradiction is avoided.

The National Oceanic and Atmospheric Administration (NOAA) provides federal leadership in marine science and conservation. The seafood industry contributes a large part of the nation's economic health, and as an agency of the US Department of Commerce, NOAA works to advance fisheries management policies and programs to ensure that fishery resources are healthy and sustainable so that they will remain a safe, nutritious, and affordable component of the US food supply. In light of these considerations, NOAA recognized the need for an independent group to examine the scientific evidence on the nutritional benefits obtained from seafood balanced against potential risks from exposure to contaminants, and ways to guide US consumers to make selections appropriate to their needs. Thus, NOAA asked the Institute of Medicine (IOM) to convene a committee with a diverse background and a broad scope of expertise to address the task put before them.

The committee was charged to identify and prioritize adverse health effects from both naturally occurring and introduced toxicants in seafood; assess evidence on availability of specific nutrients in seafood compared to other food sources; determine the impact of modifying food choices to reduce intake of naturally occurring and introduced toxicants on nutrient intake and nutritional status within the US population; develop a decision path for US consumers to balance their seafood choices to obtain nutritional benefits while minimizing exposure risks; and identify data gaps and recommend future research. The committee's report recommends approaches to decision-making for selecting seafood to obtain the greatest nutritional benefits balanced against exposure to potential toxicants, and identifies data gaps and research needs. The committee concentrated on issues affecting marine species and has not dealt in detail with freshwater fisheries.

The task has not been an easy one. The committee reviewed the existing literature on benefits of seafood consumption and has attempted to make judgments as to the strength of the evidence. In many cases, we have deemed the evidence for benefit insufficient or too preliminary. Similarly, the committee reviewed the data on contaminants and risks they imply. We were surprised at the lack of good data on the distribution of some contaminants in the seafood supply. There is likewise little available evidence as to how beneficial effects of seafood may counteract some of the risks from contaminants.

The committee also considered how consumers make decisions as to what they eat and tried to advise on how to approach the task of communicating benefits and risks to consumers. We have not regarded it the committee's task to set specific dietary standards for seafood or EPA/DHA consumption and we have considered our findings in the light of the dietary recommendations of the Dietary Guidelines Advisory Committee as well as other authoritative groups.

The Committee on Nutrient Relationships in Seafood was made up of committed members with widely varied expertise who volunteered countless hours to the research, deliberations, and preparation of the report. Many other individuals volunteered significant time and effort to address and educate our committee members during the first open session, workshop, and through consultations, and we are grateful for their contributions.

The report could not have been produced without the dedicated guidance and expertise of the study director, Ann Yaktine, and her colleagues; Cara James, research associate; and Sandra Amamoo-Kakra, senior program assistant. We also thank Geraldine Kennedo for administrative support, Greg Fulco for graphic design, and Hilary Ray for technical and copy editing. This project benefited from the support and wisdom of Linda Meyers, director of the Food and Nutrition Board.

Malden C. Nesheim, *Chair*
Committee on Nutrient Relationships in Seafood

Contents

Summary

Seafood (referring in this report to all commercially obtained fish, shellfish, and mollusks, both marine and freshwater) is a nutrient-rich food source that is widely available to most Americans. It is a good source of high-quality protein, is low in saturated fat, and is rich in many micronutrients. Seafood is often also a rich source of the preformed long-chain polyunsaturated omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which are synthesized in limited amounts by the human body from alpha-linolenic acid (ALA), a fatty acid found in several vegetable, nut, and seed oils (e.g., walnut and flaxseed oils). In the past several years, research has implicated seafood, particularly its contribution of EPA and DHA, in various health benefits identified for the developing fetus and infants, and also for adults, including those at risk for cardiovascular disease. Contamination of aquatic food sources, however, whether by naturally-occurring or introduced toxicants, is a concern for US consumers because of adverse health effects that have been associated with exposure to such compounds. Methylmercury can accumulate in the lean tissue of seafood, particularly large, predatory species such as swordfish, certain shark, tilefish, and king mackerel. Lipophilic compounds such as dioxins and polychlorinated biphenyls (PCBs) can be found in the fatty tissue of some fish. High levels of particular microbial pathogens may be present during certain seasons in various geographic areas, which can compromise the safety of products commonly eaten raw, such as oysters. Additionally, some population groups have been identified as being at greater risk from exposure to certain contaminants in seafood.

In consideration of these issues, the US Department of Commerce,

National Oceanic and Atmospheric Administration (NOAA) asked the Institute of Medicine (IOM) of the National Academies to examine relationships between benefits and risks associated with seafood consumption to help consumers make informed choices. The expert committee was asked to prioritize the potential for adverse health effects from both naturally occurring and introduced toxicants in seafood, assess evidence on availability of specific nutrients in seafood compared to other food sources, determine the impact of modifying food choices to reduce intake of naturally occurring and introduced toxicants on nutrient intake and nutritional status within the US population, develop a decision path for US consumers to weigh their seafood choices to obtain nutritional benefits balanced against exposure risks, and identify data gaps and recommend future research.

The committee concentrated primarily on seafood derived from marine (saltwater) sources and included freshwater fisheries when appropriate to the discussion. Further, the committee recognized that these sources vary greatly in their level of contamination depending on local conditions, and that individual states have issued a large number of advisories based on assessment of local conditions. Although the committee was not asked to consider questions or make recommendations about environmental concerns related to seafood, it recognizes that the impact of changes in seafood production, harvesting, and processing have important environmental consequences.

To address the task of assessing benefit-risk trade-offs, the committee took a three-step approach. The steps that framed this analytical approach were: (1) analysis and balancing of the benefits and risks (including attention to characteristics that distinguish target populations as well as substitution predictions); (2) analysis of consumer perceptions and decision-making (understanding decision contexts and their variability, and assessing consumers' behavior regarding how they perceive and make choices); and (3) design and evaluation of the decision support program itself (including format and structure of information, media, and combination of communication products and processes). The aim of the analysis in step 1 is to assess the overall effect of seafood selections rather than the assessment of reduction in a specific risk or enhancement of a specific benefit.

ANALYSIS OF THE BALANCING OF BENEFITS AND RISKS OF SEAFOOD CONSUMPTION

The scientific assessment and balancing of the benefits and risks associated with seafood consumption is a complex task. Diverse evidence, of varying levels of completeness and uncertainty, on different types of benefits and risks must be combined to carry out the assessment required as a first step in designing consumer guidance. In light of the uncertainty in the available

scientific information associated with both nutrient intake and contaminant exposure from seafood, no summary metric adequately captures the com - plexity of seafood benefit/risk trade-offs. Thus, the committee developed a four-part qualitative protocol adapted from previous work (IOM, 2003) to evaluate and balance benefits and risks. Following the protocol, the committee considered consumption patterns of seafood; the scope of the benefits and risks associated with different patterns of consumption for the population as a whole and, if appropriate, for specific target populations; and changes in benefits and risks associated with changes in consumption patterns. It then balanced the benefits and risks to come to specific guidance for healthy consumption for the population as a whole, and, as appropriate, for specific target populations.

Consumption of Seafood in the United States

Seafood consumption has increased over the past century, reaching a level of more than 16 pounds per person per year in 2003. The ten types of seafood consumed in the greatest quantities among the US general population (from highest to lowest) are shrimp, canned tuna, salmon, pol - lock, catfish, tilapia, crab, cod, clams, and flatfish (e.g., flounder and sole). The nation's seafood supply is changing, however, and this may have a significant impact on seafood choices in the future. The preference among consumers for marine types of seafood is leading to supply deficits, and seafood produced by aquaculture is replacing captured supplies for several of these types.

While seafood is recognized as a primary source of the omega-3 long-chain polyunsaturated fatty acids EPA and DHA, not all seafood is rich in these fatty acids. Among types of seafood, shrimp and canned light tuna are the two most commonly consumed, and they are not especially high in EPA and DHA. Eggs and chicken, although not particularly rich sources, [1] may contribute to the EPA and DHA content of the US diet because of their frequent consumption. Relative to other foods in the meat, poultry, fish, and eggs group, however, seafood is generally lower in saturated fatty acids and higher in EPA, DHA, and selenium, all of which have been associated with health benefits.

Primary Findings

1. Average quantities of seafood consumed by the general US popula - tion, and by several specific population groups, are below levels suggested by

[1] Because of changes in feed composition the current levels of EPA/DHA in chicken and eggs may be less than that reported in food databases.

many authoritative groups, including levels recommended by the American Heart Association for cardiovascular disease prevention; and

2. For many ethnic and geographic subgroups, there are insufficient data to characterize the intake levels of seafood, EPA, DHA, and other dietary constituents, and to assess the variability of those intakes.

Benefits Associated with Nutrients from Seafood

The high nutritional quality of seafood makes it an important component of a healthy diet. While protein is an important macronutrient in the diet, most Americans already consume enough and do not need to increase their intake. Fats and oils are also part of a healthful diet, but the type and amount of fat can be important—for example, with regard to cardiovascular disease. Many Americans consume greater than recommended amounts of saturated fat as well as cholesterol from high-fat protein foods such as beef and pork. Many seafood selections are lower in total and saturated fats and cholesterol than some more frequently selected animal protein foods such as fatty cuts of beef, pork, and poultry, and are equivalent in amount of fat to some leaner cuts of meat. Since it is lower in saturated fats, however, by substituting seafood more often for other animal foods, consumers can decrease their overall intake of both total and saturated fats while retaining the nutritional quality of other protein food choices.

Seafood is also a primary source of EPA and DHA in the American diet. The contribution of these nutrients to improving health and reducing risk for certain chronic diseases in adults has not been completely elucidated. There is evidence, however, to suggest there are benefits to the developing infant, such as increasing length of gestation, improved visual acuity, and improved cognitive development. In addition, there is evidence to support an overall benefit to the general population for reduced risk of heart disease among those who eat seafood compared to those who do not, and there may be benefits from consuming EPA and DHA for adults at risk for coronary heart disease.

Primary Findings

1. Seafood is a nutrient-rich food that makes a positive contribution to a healthful diet. It is a good source of protein, and relative to other protein foods, e.g., meat, poultry, and eggs, is generally lower in saturated fatty acids and higher in the omega-3 fatty acids EPA and DHA as well as selenium;

2. The evidence to support benefits to pregnancy outcome in females who consume seafood or fish-oil supplements as part of their diet during pregnancy is derived largely from observational studies. Clinical trials and epidemiological studies have also shown an association between increased

duration of gestation and intake of seafood or fish-oil supplements. Evidence that the infants and children of mothers who consume seafood or EPA/DHA supplements during pregnancy and/or lactation may have improved devel - opmental outcomes is also supported largely by observational studies;

3. Observational evidence suggests that increased seafood consumption is associated with a decreased risk of cardiovascular deaths and cardiovascu lar events in the general population. Evidence is insufficient to assess if this association is mediated through an increase in EPA and DHA consumption and/or a decrease in saturated fat consumption and/or other correlates of seafood consumption;

4. Evidence is inconsistent for protection against further cardiovas - cular events in individuals with a history of myocardial infarction from consumption of EPA/DHA-containing seafood or fish-oil supplements. The protection evidenced by population (observational) studies has not been consistently observed in randomized clinical trials; and

5. Evidence for a benefit associated with seafood consumption or fish-oil supplements on blood pressure, stroke, cancer, asthma, type II diabetes, or Alzheimer's disease is inconclusive. Whereas observational studies have suggested a protective role of EPA/DHA for each of these diseases, sup - portive evidence from randomized clinical trials is either nonexistent or inconclusive.

Risks Associated with Seafood

The safety of seafood in the US has increased in recent decades, although there are still a number of chemical and microbial hazards that are present in seafood. Whether a contaminant poses a health risk to consumers depends on the amount present in the food and the potential outcome from exposure. Consumers are exposed to a complex mixture of dietary and non-dietary contaminants. However, most studies of the risks associated with seafood focus on one contaminant at a time rather than a mixture. The extent to which such coexposures might affect the toxicity of seafoodborne contaminants is largely unknown. Similarly, few data are available on the extent to which beneficial components of seafood, such as selenium, might mitigate the risks associated with seafoodborne contaminants. The evidence reviewed indicates that the levels of different contaminants in seafood depend on several factors such as species, size, location, age, and feed source. Levels of some contaminants in seafood vary substantially due to their geographic localization; areas of highest variation tend to be mostly freshwater.

Consumption of aquatic foods is the major route of human exposure to methylmercury (MeHg). The seafood choices a consumer makes and the frequency with which different species are consumed are thus important determinants of methylmercury intake. Exposure to MeHg among US

consumers in general is a concern because there is uncertainty about the potential for subtle adverse health outcomes. Since the most sensitive sub-group of the population to MeHg exposure is the developing fetus, intake recommendations are developed for and directed to the pregnant woman rather than to the general population.

Persistent organic pollutants (POPs), including dioxins and PCBs, can be found in the fatty tissue of all animal-derived foods, including seafood. Exposure to these compounds among the general population has been decreasing in recent decades. The greatest concern is for population groups exposed to POPs in seafood obtained through cultural, subsistence, or recreational fishing, because of reliance on fish from locations that may pose a greater risk.

In contrast to heavy metal contaminants and POPs, the number of reported illnesses from seafoodborne microbial contaminants has remained steady over the past several decades. Exposure to *Vibrio* and *norovirus* infections is still a concern, however, because they continue to be associated with consumption of raw molluscan shellfish. Strategies for minimizing the risk of seafoodborne illnesses are, to some extent, hazard-specific, but overall include avoiding types of seafood identified as being more likely to contain certain contaminants, and following general food safety guidelines, which include proper cooking.

Primary Findings

1. Levels of contaminants in seafood depend on several factors, including species, size, harvest location, age, and composition of feed. MeHg is the seafoodborne contaminant for which the most exposure and toxicity data are available; levels of MeHg in seafood have not changed substantially in recent decades. Exposure to dioxins and PCBs varies by location and vulnerable subgroups (e.g., some American Indian/Alaskan Native groups living near contaminated waters) may be at increased risk. Microbial illness from seafood is acute, persistent, and a potentially serious risk, although incidence of illness has not increased in recent decades.

2. Considerable uncertainties are associated with estimates of the health risks to the general population from exposures to methylmercury and persistent organic pollutants at levels present in commercially obtained seafood. The available evidence to assess risks to the US population is incomplete and useful to only a limited extent.

3. Consumers are exposed to a complex mixture of dietary and non-dietary contaminants whereas most studies of risks associated with seafood focus on a single contaminant.

Balancing Benefits and Risks

From its review of consumption, benefits, and risks, the committee recommends that:

Recommendation 1: Dietary advice to the general population from federal agencies should emphasize that seafood is a component of a healthy diet, particularly as it can displace other protein sources higher in saturated fat. Seafood can favorably substitute for other high biologic value protein sources while often improving the overall nutrient profile of the diet.

Recommendation 2: Although advice from federal agencies should also support inclusion of seafood in the diets of pregnant females or those who may become pregnant, any consumption advice should stay within federal advisories for specific seafood types and state advisories for locally caught fish.

Recommendation 3: Appropriate federal agencies (the National Oceanic and Atmospheric Administration [NOAA], the US Environmental Protection Agency [USEPA], and the Food and Drug Administration of the US Department of Health and Human Services [FDA]) **should increase monitoring of methylmercury and persistent organic pollutants in seafood and make the resulting information readily available to the general public.** Along with this information, these agencies should develop better recommendations to the public about levels of pollutants that may present a risk to specific population subgroups.

Recommendation 4: Changes in the seafood supply (source and type of seafood) must be accounted for—there is inconsistency in sampling and analysis methodology used for nutrients and contaminant data that are published by state and federal agencies. Analytical data is not consistently revised, with separate data values presented for wild-caught, domestic, and imported products.

Drawing on these recommendations and its benefit-risk assessment protocol, the committee identified four population groups for which the data support subgroup-specific conclusions. In the committee's judgement, the variables that distinguish between these populations facing different benefit-risk balances based on existing evidence are (1) age, (2) gender, (3) pregnancy or possibility of becoming pregnant, or breastfeeding, and (4) risk of coronary heart disease, although the evidence for a benefit to adult males and females who are at risk for coronary heart disease is not sufficient to warrant inclusion as a separate group within the decision-making framework. The groups and appropriate guidance are listed in Box S-1 below.

To balance the benefits and risks, the recommendations, as they apply to the target population groups 1–3, are arrayed in a decision pathway (shown in Figure S-1) that illustrates the committee's resulting analysis of the balance between benefits and risks associated with seafood consumption.

BOX S-1
Population Groups and Appropriate Guidance

1. *Females who are or may become pregnant or who are breastfeeding:*
   a. May benefit from consuming seafood, especially those with relatively higher concentrations of EPA and DHA;
   b. A reasonable intake would be two 3-ounce (cooked) servings but can safely consume 12 ounces per week;
   c. Can consume up to 6 ounces of white (albacore) tuna per week;
   d. Should avoid large predatory fish such as shark, swordfish, tilefish, or king mackerel.
2. *Children up to age 12:*
   a. May benefit from consuming seafood, especially those with relatively higher concentrations of EPA and DHA;
   b. A reasonable intake would be two 3-ounce (cooked), or age-appropriate, servings but can safely consume 12 ounces per week;
   c. Can consume up to 6 ounces (or age-appropriate) of white (albacore) tuna per week;
   d. Should avoid large predatory fish such as shark, swordfish, tilefish, or king mackerel.
3. *Adolescent males, adult males, and females who will not become pregnant:*
   a. May reduce their risk for cardiovascular disease by consuming seafood regularly, e.g., two 3-ounce servings per week;
   b. Who consume more than two servings a week should choose a variety of types of seafood to reduce the risk for exposure to contaminants from a single source.
4. *Adult males and females who are at risk of cardiovascular disease:*
   a. May reduce their risk of cardiovascular disease by consuming seafood regularly, e.g., two 3-ounce servings per week;
   b. Although supporting evidence is limited, there may be additional benefits from including high EPA/DHA seafood selections;
   c. Who consume more than two servings a week should choose a variety of types of seafood to reduce the risk for exposure to contaminants from a single source.

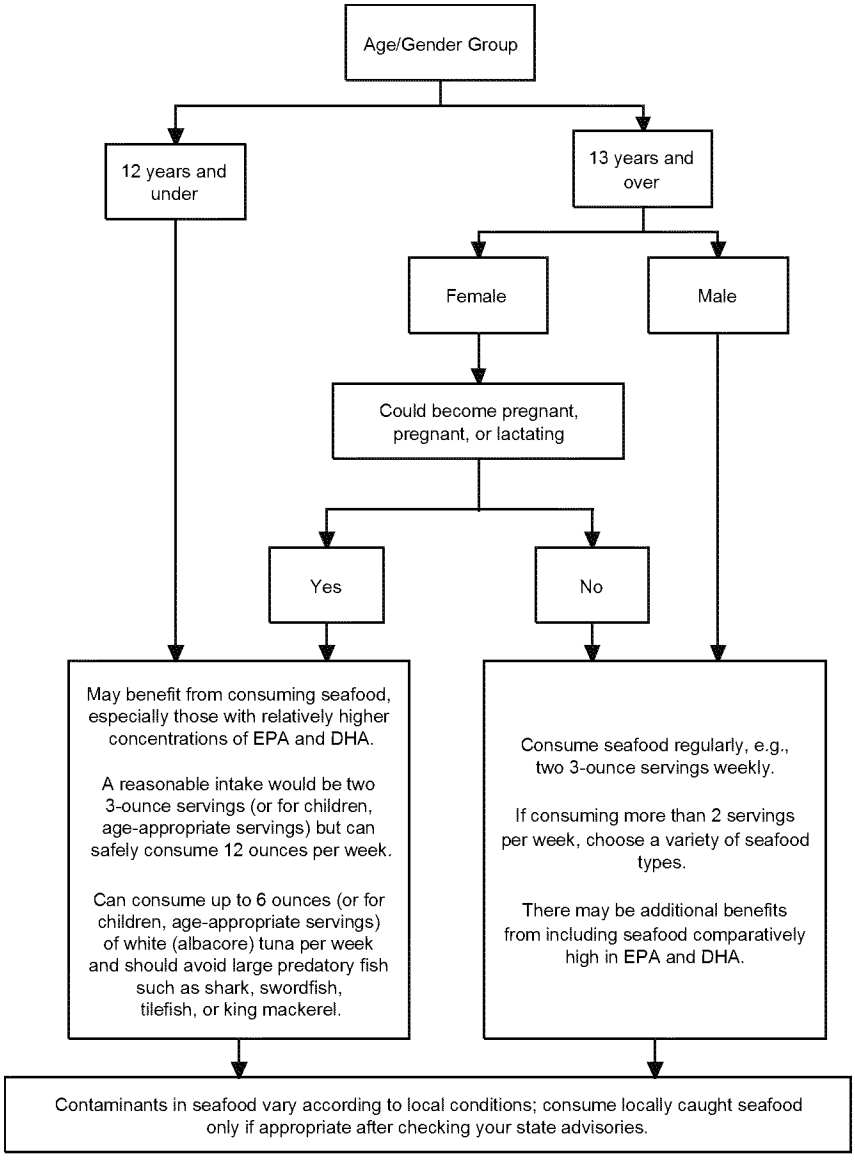

FIGURE S-1 The committee's decision pathway derived from the balance between benefits and risks associated with seafood consumption. The diagram highlights the variables that group consumers into target populations that face different benefits and risks and should receive tailored advice.
NOTE: The wording in this figure has not been tested among consumers. Designers will need to test the effects of presenting information on seafood choices in alternative formats.

UNDERSTANDING CONSUMER DECISION MAKING AS THE BASIS FOR THE DESIGN OF CONSUMER GUIDANCE

The second step in the approach to balancing benefits and risks associated with seafood consumption is developing an understanding of the context within which consumers make seafood choices. Receiving new information, such as dietary guidance, does not automatically lead consumers to change their food consumption patterns. Food choice is influenced by a complex information environment that includes taste, availability, and price, as well as guidance, point-of-purchase information, labeling, and advice from health care providers. In the context of this environment, specific pieces of guidance may have limited impact, although evidence suggests that this impact varies significantly and in many instances is not well measured or understood. There are several factors that mitigate against current advice having the intended consequences in terms of consumer choice. Increased understanding of the individual, socio-cultural, and environmental factors that influence consumer choice is necessary for the design of consumer guidance, especially where the intent is to communicate balancing of benefits and risks associated with seafood consumption.

Seafood choices, like all consumption choices, entail value trade-offs; some individuals will choose high risks to achieve what they value as high benefits (e.g., consume raw seafood because of its pleasurable taste), while others may prefer to "play it safe." Individual differences in tastes, preferences, beliefs and attitudes, and situations complicate the task of informing and supporting benefit-risk trade-off decisions. Audience segmentation and targeting, therefore, is essential for effective communication, because decision objectives, risk attitudes, and people's knowledge about and interest in decision-making vary. Guidance in making seafood choices should allow consumers to access information in a clear and easy-to-understand format. It should also be structured to support decision-making, and allow consumers to access additional layers of information when they want them.

BALANCING CHOICES: SUPPORTING CONSUMER SEAFOOD CONSUMPTION DECISIONS

The third design step for developing specific support for seafood consumption decisions is production and evaluation of the information itself, including ways to integrate the benefit and risk considerations in mock-up examples of how such information might be provided. It is apparent in any discussion of seafood consumption that "one size does not fit all" and that messages about consumption often have to be individualized for different groups, such as subsistence fishers, pregnant women, children, and native populations, to mention a few. The committee's balancing of the benefits and risks of different patterns of seafood consumption for different subpopula-

tions is illustrated in Figure S-1. Different subpopulations could be used by federal agencies as the basis for targeting advice to consumers on seafood consumption. Resulting communication products should be tested empirically. Through a brief set of questions, a decision pathway can segment and channel consumers into relevant benefit-risk subpopulations in order to provide benefit and risk information that is tailored to each group. The inclusion of alternative presentations of benefit-risk advice and information in the design of consumer advice recognizes that while some consumers prefer to follow the advice given to them by experts, others want to decide on the benefit-risk trade-offs for themselves.

One of the challenges in supporting informed consumer choice is how governmental agencies communicate health benefits and risks to both the general population and to specific subgroups or particularly vulnerable populations. Developing effective tools to disseminate current and emerging information to the public requires formal evaluation, as well as an iterative approach to design. The use of tailored messages and community-level involvement on an ongoing basis is likely to improve the effectiveness of communication between federal agencies and target populations.

Primary Findings

1. Advice to consumers from the federal government and private organizations on seafood choices to promote human health has been fragmented. Benefits have been addressed separately from risks; portion sizes differ from one piece of advice to another. Some benefits and some risks have been addressed separately from others for different physiological systems and age groups. As a result, multiple pieces of guidance—sometimes conflicting—simultaneously exist for seafood.

2. Given the uncertainties present in underlying exposure data and health impact analysis, there is no single summary metric that adequately captures the complexity of balancing benefits and risks associated with seafood for purposes of providing guidance to consumers. An expert judgement technique can be used to consider benefits and risks together, to yield specific suggested consumption guidance.

Recommendations

Recommendation 5: Appropriate federal agencies should develop tools for consumers, such as computer-based, interactive decision support and visual representations of benefits and risks that are easy to use and to interpret. An example of this kind of tool is the health risk appraisal (HRA), which allows individuals to enter their own specific information and returns appropriate recommendations to guide their health actions. The model de-

veloped here provides this kind of evidence-based recommendations regarding seafood consumption. Agencies should also develop alternative tools for populations with limited access to computer-based information.

Recommendation 6: New tools apart from traditional safety assessments should be developed, such as consumer-based benefit-risk analyses. A better way is needed to characterize the risks combined with benefit analysis.

Recommendation 7: A consumer-directed decision path needs to be properly designed, tested, and evaluated. The resulting product must undergo methodological review and update on a continuing basis. Responsible agencies will need to work with specialists in risk communication and evaluation, and tailor advice to specific groups as appropriate.

Recommendation 8: Consolidated advice is needed that brings together different benefit and risk considerations, and is tailored to individual circumstances, to better inform consumer choices. Effort should be made to improve coordination of federal guidance with that provided through partnerships at the state and local level.

Recommendation 9: Consumer messages should be tested to determine if there are spillover effects for segments of the population not targeted by the message. There is suggestive evidence that risk-avoidance advice for sensitive subpopulations may be construed by other groups or the general population as appropriate precautionary action for themselves. While emphasizing trade-offs may reduce the risk of spillover effects, consumer testing of messages should address the potential for spillover effects explicitly.

Recommendation 10: The decision pathway the committee recommends, which illustrates its analysis of the current balance between benefits and risks associated with seafood consumption, should be used as a basis for developing consumer guidance tools for selecting seafood to obtain nutritional benefits balanced against exposure risks. Real-time, interactive decision tools, easily available to the public, could increase informed actions for a significant portion of the population, and help to inform important intermediaries, such as physicians.

Recommendation 11: The sponsor should work together with appropriate federal and state agencies concerned with public health to develop an interagency task force to coordinate data and communications on seafood consumption benefits, risks, and related issues such as fish stocks and seafood sources, and begin development of a communication program to help consumers make informed seafood consumption decisions. Empirical evaluation of consumers' needs and the effectiveness of communications should be an integral part of the program.

Recommendation 12: Partnerships should be formed between federal agencies and community organizations. This effort should include targeting and involvement of intermediaries, such as physicians, and use of interactive

Internet communications, which have the potential to increase the usefulness and accuracy of seafood consumption communications.

RESEARCH GAPS AND RECOMMENDATIONS

Seafood Consumption

Recommendation 1: Research is needed on systematic surveillance studies of targeted subpopulations. Such studies should be carried out using state-of-the-art assessment methods to determine the intake levels of seafood, EPA/DHA and other dietary constituents, and the variability of those intake levels among population groups.

Recommendation 2: Sufficiently large analytic samples of the most common seafood types need to be obtained and examined. These samples should be used to determine the levels of nutrients, toxicants, and contaminants in each species and the variability between them, which should be reported transparently.

Recommendation 3: Additional data is needed to assess benefits and risks associated with seafood consumption within the same population or population subgroup.

Pregnant and Lactating Women

Recommendation 4: Better data are needed to determine if outcomes of increasing consumption of seafood or increasing EPA/DHA intake levels in US women would be comparable to outcomes of populations in other countries. Such studies should be encouraged to include populations of high fish-consumers outside the United States to determine if there are differences in risks for these populations compared to US populations.

Recommendation 5: Dose-response studies of EPA/DHA in pregnant and lactating women are needed. This information will help determine if higher intakes can further increase gestation duration, reduce premature births, and benefit infant development. Other studies should include assessing whether DHA alone can act independently of EPA to increase duration of gestation.

Infants and Toddlers

Recommendation 6: Research is needed to determine if cognitive and developmental outcomes in infants are correlated with performance later in childhood. This should include:

- Evaluating preschool and school-age children exposed to EPA/DHA in utero and postnatally, at ages beginning around 4 years when executive function is more developed; and
- Evaluating development of school-age children exposed to variable EPA/DHA levels in utero and postnatally with measures of distractibility, disruptive behavior, and oppositional defiant behavior, as well as more commonly assessed cognitive outcomes and more sophisticated tests of visual function.

Recommendation 7: Additional data are needed to better define optimum intake levels of EPA/DHA for infants and toddlers.

Children

Recommendation 8: Better-designed studies about EPA/DHA supplementation in children with behavioral disorders are needed.

Adults at Risk for Chronic Disease

Recommendation 9: In the absence of meta-analyses that systematically combine quantitative data from multiple studies, further meta-analyses and larger randomized trials are needed to assess outcomes other than cardiovascular, in particular total mortality, in order to explore possible adverse effects of EPA/DHA supplementation.

Recommendation 10: Additional clinical research is needed to assess a potential effect of seafood consumption and/or EPA/DHA supplementation on stroke, cancer, Alzheimer's disease, and depression.

Recommendation 11: Future epidemiological studies should assess intake of specific species of seafood and/or biomarkers, in order to differentiate the health effects of EPA/DHA from the health effects of contaminants such as methylmercury.

Health Risks Associated with Seafood Consumption

Recommendation 12: More complete data are needed on the distribution of contaminant levels among types of fish. This information should be made available in order to reduce uncertainties associated with the estimation of health risks for specific seafoodborne contaminant exposures.

Recommendation 13: More quantitative characterization is needed of the dose-response relationships between chemical contaminants and adverse health effects, in the ranges of exposure represented in the general US population. Such information will reduce uncertainties associated with recommendations for acceptable ranges of intake.

Recommendation 14: In addition, the committee recommends more research on useful biomarkers of contaminant exposures and more precise quantitative characterization of the dose-response relationships between chemical contaminants and adverse health effects, in the ranges of exposure represented in the general US population, in order to reduce uncertainties associated with recommendations for acceptable ranges of intake.

Designing Consumer Guidance

Recommendation 15: Research is needed to develop and evaluate more effective communication tools for use when conveying the health benefits and risks of seafood consumption as well as current and emerging information to the public. These tools should be tested among different communities and subgroups within the population and evaluated with pre- and post-test activities.

Recommendation 16: Among federal agencies there is a need to design and distribute better consumer advice to understand and acknowledge the context in which the information will be used by consumers. Understanding consumer decision-making is a prerequisite. The information provided to consumers should be developed with recognition of the individual, environmental, social, and economic consequences of the advice. In addition, it is important that consistency between agencies be maintained, particularly with regard to communication information using serving sizes.

CONCLUSION

For most of the general population, balancing benefits and risks associated with seafood consumption to obtain nutritional and health benefits can be achieved by selecting seafood from available options in quantities that fall within accepted dietary guidelines. For the specific subgroups identified by the committee, making such selections requires that consumers are aware of both nutrients and contaminants in the seafood available and are provided useful information on both benefits and risks to inform their choices. The committee has put forward its interpretation of the evidence for benefits and risks associated with seafood and considered the balance between them. Recommendations are made to facilitate development of appropriate consumer guidance for making seafood selections, based on the committee's findings, and research opportunities are identified that will contribute to filling knowledge gaps.

1

Introduction

Federal agencies and private organizations have recommended including seafood as part of a healthy diet because of the variety of nutrients it provides. However, contamination of seafood, whether by naturally occurring or introduced contaminants, remains a concern for US consumers because of the potential for adverse health effects. The extent to which a contaminant in a food may be considered a risk to health depends upon the nature and level of the compound present, and the sensitivity of individuals or groups in a population to potentially toxic compounds. Specific population groups have been identified as being at particular risk from exposure to contaminants in seafood. Paradoxically, these population groups may especially benefit from the nutrients in seafood. For most of the general population, optimal benefits from seafood can be obtained by making choices to maximize intake of desirable nutrients balanced against exposure to contaminants that may pose a health risk. Making such selections, however, requires that consumers are aware of the variety of seafood available and are provided information on both benefits and risks to inform their choices.

For the purposes of this report, the term seafood refers to all commercially obtained fish, shellfish, and mollusks, both marine and freshwater. When marine mammals are pertinent to the discussion, they will be identified separately. The impact of seafood obtained by subsistence and recreational harvesting is considered as far as the more limited data allow.

RECOMMENDATIONS TO ENCOURAGE SEAFOOD CONSUMPTION

Seafood contributes a variety of nutrients to the American diet, including protein and important micronutrients, and its eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) content distinguishes it as providing a unique nutritional benefit. EPA and DHA are abundant in some seafood types and the conversion from alpha-linolenic acid (ALA) is inefficient in humans (Burdge, 2004). Seafood is not a primary source for ALA. EPA and DHA are believed to be important in reducing the risk of cardiovascular disease, lengthening gestation, and possibly promoting fetal and infant neurological development. For these reasons, several groups have recommended inclusion of seafood, particularly those choices high in EPA/DHA, in the American diet (see Appendix Table B-3). These recommendations frequently refer to servings per week; throughout this report, unless otherwise stated, a serving of seafood is defined as 4 ounces raw, which yields 3 ounces cooked. As noted later in this chapter and throughout the report, some federal and state agencies and nonfederal organizations include larger (8 ounce) serving sizes in their recommendations and advisories. This committee has adopted the convention of the Dietary Guidelines Advisory Committee (see below) in considering a serving size from the meat, poultry, fish, and egg food group to be 4 ounces raw, or 3 ounces cooked.

Dietary Guidelines Advisory Committee

Every 5 years, an expert Dietary Guidelines Advisory Committee (DGAC) is appointed to make recommendations to the Secretaries of the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) concerning revision of the *Dietary Guidelines for Americans* (DGA). In 2005, the DGAC issued its own report, separate from the Dietary Guidelines, which reviewed the preponderance of scientific and medical knowledge and suggested a set of key messages (DGAC, 2005).

One of these messages, in the section on dietary fats, was "the consumption of two servings (approximately 6–8 ounces) per week of fish high in EPA and DHA is associated with reduced risk of both sudden death and death from coronary heart disease in adults. To benefit from the potential cardioprotective effects of EPA and DHA, the weekly consumption of two servings of fish, particularly fish rich in EPA and DHA, is suggested. Other sources of EPA and DHA may provide similar benefits; however, further research is warranted." The strength of this message was tempered somewhat by the section on food safety, which warned of the potential danger of methylmercury in fish.

Dietary Guidelines for Americans

The *Dietary Guidelines for Americans* provide science-based advice to promote health and reduce risk for major chronic diseases through diet and physical activity. The DGA are a statement of federal nutrition policy and, as such, form the basis of all federal food assistance as well as nutrition education and information programs. For example, the DGA are used in menu planning in the National School Lunch Program; in educational materials used by the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC); and in setting the Healthy People objectives for the nation. In addition, the Secretaries of HHS and USDA review all federal publications related to dietary guidance to ensure consistency with the DGA.

Developed for policy makers, nutrition professionals, and educators, the DGA were initially published in 1980 by HHS and USDA, and have been updated every 5 years. The most recent edition was drafted in 2005 by a committee of scientists after reviewing the recommendations of the DGAC (see above) and the associated public comments. Because of the competing benefits and risks associated with seafood consumption pointed out in the DGAC report, drafters of the DGA stopped short of making a quantified key recommendation for fish or seafood. Instead, they recommended that individuals "Keep total fat intake between 20 to 35 percent of calories, with most fats coming from sources of polyunsaturated and monounsaturated fatty acids, such as fish, nuts, and vegetable oils" (DGA, 2005). The accompanying text cites evidence for a reduced risk of cardiovascular disease among the general population associated with the consumption of certain fatty acids from seafood.

MyPyramid

After the release of the DGA, the USDA released the MyPyramid food guidance system along with the new MyPyramid symbol (USDA, 2005). This food guidance system was developed to help Americans make healthy food choices, given their sex, age, and activity level. Recommended quantities are provided for each food group (grains, fruits, vegetables, milk, meat and beans, oils, and discretionary calories), with fish represented in the meat and beans group. While no specific quantity of fish is recommended, "selection tips" suggest that Americans "select fish rich in omega-3 fatty acids, such as salmon, trout, and herring, more often" (Source: http://www.mypyramid.gov).

American Heart Association Guidelines

The American Heart Association (AHA) Dietary Guidelines are based on the findings of the nutrition committee of the AHA and were last revised

TABLE 1-1 Summary of American Heart Association Recommendations for Omega-3 Fatty Acid Intake[a]

Population	Recommendation
Patients without documented coronary heart disease (CHD)	Eat a variety of (preferably fatty) fish at least twice a week. Include oils and foods rich in alpha-linolenic acid (flaxseed, canola, and soybean oils; flaxseed and walnuts).
Patients with documented CHD	Consume about 1 g of EPA+DHA per day, preferably from fatty fish. EPA+DHA supplements could be considered in consultation with the physician.
Patients who need to lower triglycerides	2 to 4 g of EPA+DHA per day provided as capsules under a physician's care.

[a]Patients taking more than 3 g of omega-3 fatty acids from supplements should do so only under a physician's care. High intakes could cause excessive bleeding in some people.

SOURCE: AHA, 2005.

in 2000 (Krauss et al., 2000). The AHA recommendations are aimed at reducing risk for cardiovascular disease by altering dietary and lifestyle factors among the general population, although there are individualized approaches for specific subgroups with medical concerns such as lipid disorders and diabetes. The AHA dietary guidelines include a recommendation that healthy adults eat fish at least twice a week. Altogether, the AHA has three recommended intake levels for EPA and DHA, corresponding to research findings on associations between EPA/DHA intake and cardiac risk reduction. The AHA (2005) recommendations, posted on its website (Source: http://www.americanheart.org/presenter.jhtml?identifier=851), are shown in Table 1-1.

The basis for the AHA recommendations is research suggesting that adopting healthy food habits that include eating two 3-ounce servings of seafood per week can help reduce three major risk factors for heart attack—high blood cholesterol, high blood pressure, and excess body weight (see Chapter 3 for discussion). Reducing blood pressure may also help reduce the major risk factors for stroke. Recognizing the importance of primary prevention, i.e., preventing the development of cardiovascular risk factors before symptoms arise, the American Heart Association also endorses the recommendation that children aged 2 years and above increase consumption of "oily" fish prepared by broiling or baking (Gidding et al., 2005).

The American Dietetic Association

The American Dietetic Association and the Dietitians of Canada (ADA, 2003) published a position paper on vegetarian diets that addressed inclusion of omega-3 fatty acids. Vegetarian diets, which are rich in omega-6

but poor in omega-3 fatty acids, may contribute to decreased production of EPA and DHA in vegetarians. Apart from fish and eggs, omega-3 fatty acids can be obtained from microalgae, which is now available as a dietary supplement.

The Dietary Reference Intake (IOM, 2002/2005) recommendation for an adequate intake (AI) of 1.6 and 1.1 grams of ALA per day for men and women, respectively, assumes some intake of EPA and DHA to meet targeted omega-3 levels. However, since vegetarians may not consume adequate levels of preformed EPA and DHA from seafood, and ALA is not efficiently converted to EPA/DHA, this recommendation may not be adequate for their needs. The joint World Health Organization/Food and Agriculture Organization *Consultation on Diet, Nutrition and the Prevention of Chronic Disease* (WHO/FAO, 2003) recommendation of an intake of 5–8 percent of daily calories from omega-6 and 1–2 percent from all omega-3 (EPA, DHA, and ALA) sources also falls short of vegetarians' needs if an algal source is not included in the diet.

The position of the American Dietetic Association is that vegetarians should include good sources of ALA, such as flaxseed, flaxseed oil, soy, or walnut oil in their diets. In addition, for those with increased requirements, including pregnant and lactating females, direct sources of EPA and DHA such as microalgae should be included in the diet.

ADVISORIES AND WARNINGS ABOUT SEAFOOD CONSUMPTION

The levels of different toxic compounds in seafood vary within and among species due to the chemical properties of the contaminant and the characteristics of the seafood. For example, compounds such as dioxins and polychlorinated biphenyls (PCBs) accumulate in fat tissue and are found predominantly in fatty fish and fish that live in fresh or coastal waters, including striped bass, bluefish, American eel, lake trout, and farmed Atlantic salmon. Heavy metals such as methylmercury accumulate in lean tissue and are found in the muscle tissue of older, predatory fish such as shark, swordfish, king mackerel, and tilefish.

Federal Advisories

The Food and Drug Administration (FDA) of the US Department of Health and Human Services announced in 2001 its advice to pregnant females and those of childbearing age who may become pregnant on the hazard of consuming fish that may contain high levels of methylmercury. In 2004, the advice was jointly reissued by FDA and the US Environmental Protection Agency (US EPA), and was updated to include the message that seafood makes an important contribution to the diet (US EPA/FDA, 2004).

The FDA advice states that women should select a variety of seafood including shellfish, canned fish, smaller ocean fish or farm-raised fish, and that they could safely consume 12 ounces per week of cooked fish (four 3-ounce servings). The US EPA/FDA joint advisory also includes information on specific types of fish that are low or high in methylmercury and advice to consumers to check their local advisories about the safety of locally caught fish. The advisory further cautions pregnant women and women of child-bearing age who may become pregnant, as well as women who are nursing and young children, to avoid consuming shark, swordfish, king mackerel, and tilefish. This recommendation applies to commercially obtained as well as consumer-caught fish. The US EPA national fishing advisory states that, for consumer-caught fish, consumers should first consult their local advisories, or in the case where no advisory exists, to restrict consumption of consumer-caught fish to one "8-ounce (raw; 6 ounces cooked) meal per week" (US EPA, 2004a) for an adult with a body weight of 70 kilograms (kg) (154 pounds) (see Table 1-2).

State Advisories

The five primary bioaccumulative pollutants for which fishing advisories have been established are mercury, PCBs, chlordane, dioxins, and DDT and its metabolites, although approximately 76 percent of all advisories issued addressed mercury contamination. States establish their own advisory criteria, which may be based on established federal advisories, and determine which water bodies to monitor; these may include coastal waters, rivers, and lakes. Across the states and territories of the United States, the number of waterbodies under advisory represents 35 percent of total lake acres (approximately 101,818 lakes), 24 percent of total river miles (approximately 846,310 river miles), and 71 percent of the contiguous coastal waters (US EPA, 2004b).

The National Listing of Fish Advisories database (Source: http://www.epa.gov/waterscience/fish/advisories/index.html) listed 3,089 advisories in 48 states, the District of Columbia, and the US Territory of American Samoa in 2003 (US EPA, 2005b).

In 2003, 31 states had statewide advisories in effect, including new statewide advisories for all rivers and lakes in Montana and Washington, and an advisory for marine fish in Hawaii. In addition to advisories in place in 2003, 16 states across the United States had Safe Eating Guidelines, either for specific waterbodies or inclusive of all rivers and lakes statewide. The guidelines are issued to inform and reassure the public that certain species of fish taken from these waterbodies have been tested and shown to contain very low levels of contaminants. The only state within the continental United States that did not have an advisory of any type in 2003 was Wyoming

TABLE 1-2 Federal Fish Advisories in the United States

Organization	Audience	Reasons for Advisories/Restrictions	Fish Advisories/Restrictions[a]		
			Type of Fish/Seafood	Serving Size	Number of Servings
Environmental Protection Agency	Not specified	Inform the public from which specific bodies of water or which species of fish it is safe to eat	Noncommercial fish (where there is no local advisory)	8 ounces raw (6 ounces cooked)[b]	Once per week
Food and Drug Administration	Pregnant women and women of childbearing age	Receive the benefits of eating fish and shellfish and be confident of reductions in exposure to the harmful effects of methylmercury	A variety of fish includes shellfish, canned fish, smaller ocean fish, or farm-raised fish	6 ounces cooked	Twice per week
Environmental Protection Agency and Food and Drug Administration	Pregnant women, women of childbearing age, nursing women, and children	These fish contain high levels of methylmercury	Shark, swordfish, king mackerel, tilefish	Any	Avoid
Environmental Protection Agency and Food and Drug Administration	Pregnant women, women of childbearing age, nursing women, and children	Albacore ("white") tuna has more methylmercury than canned light tuna	Albacore ("white") tuna and locally caught fish	6 ounces	Once per week[c]

[a]When consuming noncommercial fish, always check for local fishing advisories.
[b]For an adult with an average body weight of 70 kilograms (154 pounds), based on a reference dose for methylmercury of 1×10^{-4} mg/kg/day.
[c]If consuming locally caught fish, do not consume any other fish that week.

SOURCES: USEPA, 2004a; FDA, 2001; USEPA/FDA, 2004.

(Source: http://www.epa.gov/waterscience/fish/advisories/fs2004.html). The number of total state and territory advisories increased to 3,221 in 2004; however, the number of Safe Eating Guidelines issued by states increased as well to 1,213 in 2004.

ADVICE ON SEAFOOD CONSUMPTION OUTSIDE THE US

The United Kingdom's Scientific Advisory Committee on Nutrition

In the United Kingdom (UK), the Food Standards Agency (FSA) and the Department of Health sought advice from the Scientific Advisory Committee on Nutrition (SACN) and the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) on the benefits and risks of fish consumption, with particular reference to "oily" fish (fish high in EPA/DHA). A joint SACN/COT subgroup was convened to deliberate and produce a report. The report (SACN, 2004) assessed the risks associated with consumption of seafood, weighed the nutritional benefits against possible risks, and developed coherent dietary advice for the public on the consumption of seafood.

A summary of the benefits and risks associated with seafood consumption was reviewed in the report. Among the conclusions reached by the SACN/COT regarding those benefits and risks associated with increased consumption of seafood and fish oils were that:

1. SACN endorsed the general population recommendation to eat at least two servings of fish per week, of which one should be oily, and agreed that this recommendation should also apply to pregnant women;
2. An increase in oily fish consumption to one serving a week, from the current levels of about a third of a serving a week, would probably confer significant public health benefits in terms of reduced risk of cardiovascular disease;
3. There is further evidence that increased seafood consumption might have beneficial effects on fetal development;
4. The evidence to support benefits at higher levels of consumption is insufficient to enable accurate quantification; and
5. Exceeding designated intake guideline ranges over the short-term would not be deleterious, but long-term exceedances could have deleterious effects in sensitive individuals. In the case of pregnant and lactating women, for example, a woman who had not consistently exceeded the guideline range previously, could increase her oily fish consumption throughout pregnancy and lactation above the guideline range (e.g., to two to three servings of oily fish a week) without detrimental effects from exposure to persistent organic pollutants such as dioxins and PCBs.

The European Food Safety Authority

Recognizing that fish is a source of nutritional benefit but also of contaminants of concern, particularly methylmercury, dioxins, and dioxin-like compounds (DLCs), the European Food Safety Authority (EFSA) was asked by the European Parliament to assess health risks associated with consumption of farmed and wild-caught fish, including an assessment of the safety of consuming Baltic herring (EFSA, 2005a). EFSA reviewed evidence on the benefits of nutrients, especially omega-3 fatty acids, in fish; sources of contaminants of concern in seafood; and risks to health from consuming fish and generated exposure scenarios from data on consumption of and contaminants in fish. The conclusions and recommendations of EFSA were published as an opinion on the health risks related to consumption of wild and farmed fish (Source: http://www.efsa.eu.int/science/contam/contam_opinions/1007_en.html).

The report pointed out that fish obtained from the Baltic Sea are likely to contain higher levels of contaminants, particularly dioxins and PCBs, than comparable fish obtained from other sources. For some EU member countries, i.e., Sweden and Finland, there is specific national advice for consumers, particularly girls (due to childbearing potential), about consuming Baltic fish that may be contaminated with dioxins and PCBs. Apart from fish obtained from the Baltic Sea, the EFSA opinion states that there are no consistent differences between wild and farmed fish regarding either safety or nutritional value, and that consumption of fish, especially fish high in EPA/DHA, is beneficial to cardiovascular health and to fetal development.

The report noted that fish is a valuable source of many nutrients, including protein, iodine, selenium, and vitamins A and D. The EFSA statement was further qualified, however, with the advice that vulnerable population groups, such as pregnant women and women of childbearing age, should consider the nutritional benefits of fish weighed against potential risks from contaminants in certain types of fish. The EFSA panel also stated that advice regarding fish consumption should take into account other comparable sources of contaminants, particularly dioxin-like compounds and PCBs, that are present in the fatty components of other animal foods. Pregnant women were advised to consume up to two servings of fish per week as long as certain types of fish, e.g., long-lived predatory fish such as swordfish and tuna, were avoided (for additional information see Cossa et al., 1989; Claisse et al., 2001). Lastly, the EFSA panel recommended development of a consistent and agreed-upon methodology for carrying out quantitative assessments of benefits and risks related to food consumption.

World Health Organization

A Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases met in Geneva in 2002 to evaluate evidence for the role of diet in the prevention of nutritional deficiency and chronic disease. The Joint WHO/FAO committee's report *Diet, Nutrition and the Prevention of Chronic Diseases* recommends a shift in the conceptual framework for developing health care strategies that would place nutrition, together with the other principal risk factors for chronic disease, at the fore front of public health policies and programs (WHO/FAO, 2003).

The report examined the role of omega-6 and omega-3 fatty acids in the prevention of chronic disease, including cancer and cardiovascular dis - ease. Recommendations included that diets should provide a total intake of omega-6 and omega-3 fatty acids in the range of 6–10 percent of daily energy (caloric) intake, but an optimal balance would include 5–8 percent of those percent as n-6 and 1–2 percent as n-3 fatty acids. Omega-3 fatty acids include ±-linolenic (ALA), eicosapentaenoic (EPA), and docosahexaenoic (DHA). Whereas certain fish are the primary source of EPA and DHA, ALA is derived primarily from plant sources, e.g., soybean, flaxseed, and walnut oils. The WHO/FAO (2003) recommendation on the consumption of fish is that "Regular fish consumption (1–2 servings per week) is protective against coronary heart disease and ischaemic stroke and is recommended. The serving should provide an equivalent of 200–500 mg of eicosapentaenoic and docosahexaenoic acid. People who are vegetarians are recommended to ensure adequate intake of plant sources of ±-linolenic acid."

THE CHARGE TO THE COMMITTEE

Considering the recommendations and suggestions to increase seafood intake to promote cardiovascular health, and the somewhat conflicting messages to avoid certain fish, consumers and health professionals may feel confused regarding the healthfulness of consuming seafood. For this reason, the National Marine Fisheries Service (NMFS) of the Department of Commerce, National Oceanic and Atmospheric Administration (NOAA), in particular the National Marine Fisheries Science Board, asked the Institute of Medicine to convene an ad hoc committee to (1) identify and prioritize the potential for adverse health effects from both naturally occurring and introduced toxicants in seafood, (2) assess evidence on availability of spe - cific nutrients in seafood compared to other food sources, (3) determine the impact of modifying food choices to reduce intake of naturally occurring and introduced toxicants on nutrient intake and nutritional status within the US population, (4) develop a decision path, appropriate to the needs of US consumers, for selecting seafood to balance their choices to obtain

nutritional benefits against exposure risks, and (5) identify data gaps and recommend future research.

Many of the contaminants that are present in seafood and have a role in influencing selections to balance benefits and risks are introduced, and thus may be controlled. For this reason, an examination of the sources of toxicants and the pathways by which they enter and bioaccumulate in the seafood supply is important. However, the committee was not asked to make recommendations to mitigate contaminant sources in seafood.

Approach to the Task

Following a request by NOAA to the National Academies, an expert committee was appointed to review evidence on ways for the US consumer to balance the benefits of seafood consumption against potential risks from exposure to contaminants they may contain, and to recommend ways to guide US consumers in making selections appropriate to their needs. The committee approached its task by gathering information from existing literature and from workshop presentations by recognized experts (see Appendix D for workshop agendas), consulting with experts in relevant fields, performing analyses on data collected in the most recent National Health and Nutrition Examination Survey (NHANES), deliberating on issues relevant to the task, and formulating an approach to address the scope of work.

ORGANIZATION OF THE REPORT

This report is organized into seven chapters that describe what is known about the benefits associated with nutrients in seafood, particularly omega-3 fatty acids; risks associated with contaminants found in seafood; and ways to balance benefits and risks and guide consumers in making selections appropriate to their needs. Chapter 2 provides information on seafood consumption patterns, and nutrients and contaminants in seafood. Chapter 3 provides in-depth evaluation of the literature on benefits of consuming seafood, particularly omega-3 fatty acids, and the impact of seafood consumption on health outcomes. Chapter 4 reviews risks associated with introduced and naturally occurring contaminants in seafood and potential health outcomes from exposure. Chapter 5 discusses the scientific assessment and analysis of risks and benefits from seafood consumption and ways that benefits and risks could vary depending on the type of fish consumed. Chapter 6 discusses consumer decision-making and the current consumer information environment and Chapter 7 discusses approaches to designing consumer information and supporting seafood consumption decisions.

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2

Consumption Patterns and Composition of Seafood

This chapter provides a discussion of seafood consumption in terms of trends over time, major types of seafood, and current intake among the general population and various subgroups. This is followed by a discussion of future trends in seafood supplies that may have an impact on seafood selections. The discussion then reviews information on the consumption and sources of nutrients, particularly the omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), because seafood is their primary source in the US diet. Finally, the overall nutrient profiles of seafood are compared to those of other foods in the diet.

SEAFOOD CONSUMPTION

Trends over Time

Trends in seafood consumption can be tracked using national food supply data. These data are especially useful because the methodology for collecting and analyzing them has remained consistent for nearly 100 years. Per capita seafood consumption is calculated by the National Marine Fisheries Service (NMFS) of the Department of Commerce using a disappearance model. This model estimates, on an annual basis, the total US supply of imported and landed seafood converted to raw edible weight, minus exports and other decreases in supply. The edible supply determined by this method is then divided by the total population to estimate per capita consumption (Source: http:// www.nmfs.noaa.gov). The estimate can be considered an upper bound of seafood consumption, because some amount

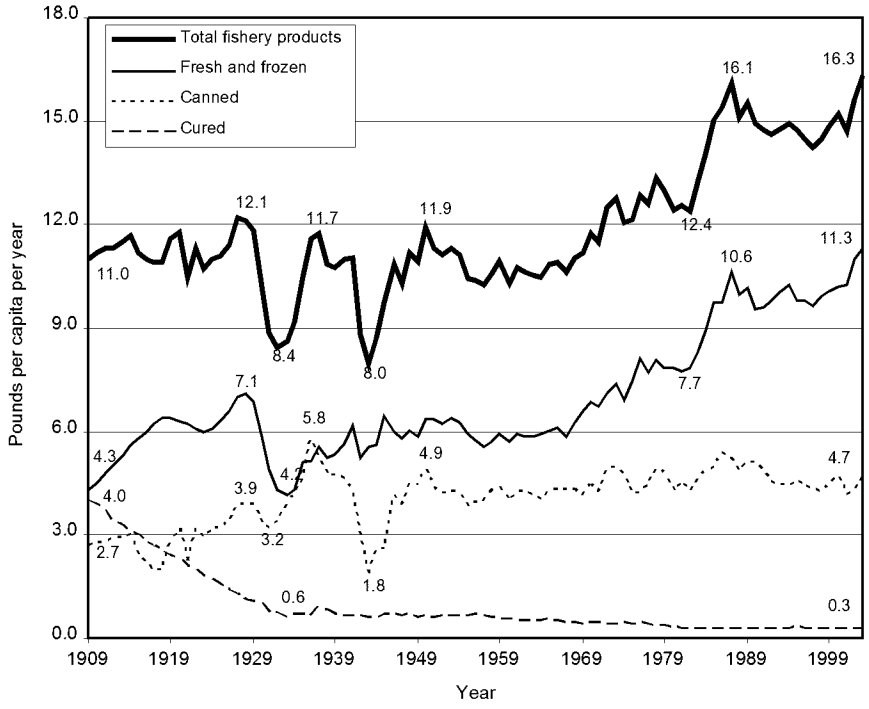

FIGURE 2-1 Trends in US consumption of total fishery products, by type (boneless, trimmed [edible] weight), in pounds per capita per year, 1909–2003. Figures are calculated on the basis of edible raw meat. Excludes edible offal, bones, and viscera for fishery products. Excludes game consumption for fishery product. Calculated from data not rounded.
SOURCE: ERS, 2004.

of the product is wasted at the household level. As shown in Figure 2-1, seafood consumption has increased since 1909, with notable exceptions during the Depression and the Second World War. In 2003, per capita seafood consumption was 16.3 pounds per person (Source: http://www.ers.usda.gov/data/foodconsumption/spreadsheet.mtfish.xls). As can be seen from Figure 2-1, the increase in seafood consumption results from an increase in consumption of fresh and frozen forms rather than canned and cured seafood.

Major Types of Seafood

There are several ways to consider the major types of seafood consumed, as shown in Tables 2-1 through 2-3. NMFS data are useful for

TABLE 2-1 NMFS Disappearance Data Ranked by Seafood Type for 2004 and 1994

	2004		1994	
Rank	Fish	Estimated Per Capita Consumption (pounds)	Fish	Estimated Per Capita Consumption (pounds)
1	Shrimp	4.2	Canned tuna	3.3
2	Canned tuna	3.3	Shrimp	2.5
3	Salmon	2.2	Pollock	1.5
4	Pollock	1.3	Salmon	1.1
5	Catfish	1.1	Cod	0.9
6	Tilapia	0.7	Catfish	0.9
7	Crab	0.6	Clams	0.5
8	Cod	0.6	Flatfish	0.4
9	Clams	0.5	Crab	0.3
10	Flatfish[a]	0.3	Scallops	0.3

NOTES: The figures are calculated on the basis of raw, edible meat, that is, excluding such offals as bones, viscera, and shells. Excludes game fish consumption.

[a]Includes flounder and sole.

SOURCE: NFI, 2005.

examining the top species entering retail distribution channels in a given year. Table 2-1 shows estimated US per capita consumption calculated from disappearance data by type of seafood for 1994 and 2004. Over this decade, shrimp and tuna remained the most frequently consumed seafood; the top

TABLE 2-2 Percentage of Persons (Aged 2 and Older) Reporting Having Eaten Different Types of Seafood in Last 30 Days, 1999–2000

Rank	Seafood Type	Percent Consuming
1	Shrimp	84.6
2	Tuna	49.1
3	Crab	25.3
4	Breaded fish[a]	23.6
5	Salmon	20.2
6	Clams	15.2
7	Catfish	14.9
8	Scallops	13.2
9	Lobster	12.3
10	Oysters	10.1

[a]Breaded fish, although not identified by type, is commonly pollock, which explains its high ranking among the top 10 seafoods consumed.

SOURCE: CDC/NCHS, 1999/2000.

TABLE 2-3 Proportion of Total Seafood Consumed on a Given Day, for Various Types of Seafood, 1999–2000

Rank	Seafood Type	Percent Consumed
1	Tuna	22.1
2	Shrimp	16.1
3	Salmon	8.9
4	Mix of fish	8.1
5	Crab	7.5
6	Cod	5.1
7	Flounder	4.5
8	Catfish	4.2
9	Don't know type	3.4
10	Clams	2.4

SOURCE: DGAC, 2005.

ten seafood types were consistent, except that tilapia replaced scallops. The data represented in Table 2-1 does not take into account possible regional differences in seafood consumption. Rupp et al. (1980) reported that most regional differences in seafood consumption were attributable to freshwater and shellfish. Generally, consumption of freshwater species was greater in inland compared to coastal regions. Miller and Nash (1971) reported that overall shellfish consumption was greater in coastal regions, but the species consumed varied between northern and southern coastal areas, e.g., consumption of clams was greater in New England whereas consumption of oysters was greater in South Atlantic and Pacific states.

Another way of considering the top seafood is to compare the percentage of the population having eaten different types of seafood. In 1999–2000, the National Health and Nutrition Examination Survey (NHANES) queried respondents about their frequency of consumption of various seafood types in the previous 30 days. Table 2-2 provides a ranking of these by the percentage reporting consumption at least once. Consistent with the NMFS data, shrimp and tuna are the types consumed by the largest percentage of respondents, and crab, salmon, clams, catfish, scallops, and cod are included among the top choices. "Breaded fish" is not identified by type, and could represent some double-counting with other types, but is of interest for its relatively high use and caloric density.

Finally, another indication of the top types of seafood can be gleaned from the 1999–2000 NHANES 24-hour recalls of dietary intake. While respondents report seafood consumption in various ways—consumed with or without other ingredients added—the seafood portion alone can be examined by disaggregating all the ingredients using the US Department of Agriculture's (USDA) FoodLink database. Table 2-3 provides the major types of seafood consumed in the United States, using food intake data from

all respondents aged 2 years and over. The types of seafood accounting for the greatest proportion consumed on a given day were tuna, about 22 percent; shrimp, about 16 percent; salmon, about 9 percent; mixed fish, about 8 percent; and crab, about 7 percent (DGAC, 2005).

The congruence of disappearance and consumption data on the types of seafood consumed in the diet of the US population provides a solid basis from which to make recommendations for consumer choices. Notably, the four fish (shark, swordfish, king mackerel, and tilefish) identified in federal advisories (US EPA/FDA, 2004) as those which pregnant women should avoid eating are not among those that are widely consumed by the general population.

It should also be noted that tuna consumption shown on Tables 2-1 to 2-3 represents an aggregate of both "light" and "white" tuna. According to the USDA, approximately 75 percent of tuna consumed is light and 25 percent is white (DGAC, 2005). Substantial differences exist between light and white tuna, in both fatty acid composition and potential toxicants (see Box 2-1). The significance of this aggregation will become evident in the following discussions.

Current Seafood Intake by the General Population

Food intake data obtained using 24-hour recalls from a representative sample are generally considered the best source of point estimate consumption data for a population. As shown in Table 2-4, about 16 percent of individuals consume some seafood on a given day, with the average quantity consumed being 89 grams (g) or approximately 3 ounces. These are quantities reported as eaten, so they generally represent cooked weights. Adult males and pregnant/lactating women whose intake was at or above the 95th percentile of quantities consumed reported intakes exceeding 280 g or about 10 ounces for days they consumed seafood.

The percentage of individuals consuming seafood varies among age groups, with children and adolescents being least, and those aged 40 to 59 years most, likely to consume seafood on a given day. Within each age category, there is little difference between the percentage of males and females consuming seafood. If the entire population consumed two 3-ounce servings (4 ounces raw) per week, the average quantity consumed per person per day would be expected to be 24 g per day (28 g per ounce × 6 ounces per week/7 days per week). Table 2-4 shows that no groups averaged this level of intake, and few groups even came close. These data suggest that seafood consumption for most individuals in the population is below targeted intake levels. Further, the committee recognizes that because of limitations in the supply of available seafood along with reported seafood consumption pat-

BOX 2-1
Tuna: White vs. Light

Tuna is the most popular fish used for canning and is the second most consumed type of seafood in the United States. Japan and the United States consume 36 and 31 percent, respectively, of the global tuna catch.

Tuna is a predatory fish that, if consumed in large quantities, may contain levels of methylmercury that exceed recommended safe levels. Although many different tuna species are fished, the most popular commercial varieties are described below.

White Tuna
Albacore—high in fat and rich in EPA/DHA; it has the whitest flesh and is typically referred to as white tuna; it is eaten both canned and fresh. Albacore generally contains more methylmercury than other types of tuna and may also contain more lipophilic compounds.
Northern Bluefin—high in fat and EPA/DHA; it is a slow-growing and thus rarer species than albacore and has a very high-quality meat; its major market is Japan, where it is used for sashimi.
Southern Bluefin—stocks are in decline and thus it is harder to obtain than other tunas. It is the most expensive fresh tuna.

Light Tuna
Skipjack—leaner than albacore tuna; it is the most commonly used tuna for canning.
Yellowfin—larger and leaner than albacore; it has pale pink flesh and is the second most popular species of tuna used in canning.
Bigeye—similar to yellowfin; it has a milder flavor than skipjack or yellowfin and is frequently used in canning.

Most canned tuna sold in the United States is available as "solid," also called "fancy" (a solid piece of loin, cut to fit the can); or "chunk" (a mixture of cut pieces). Canned tuna comes packed in either oil or water and is labeled either "white" or "light." Chunk light tuna packed in water is the most popular form of canned tuna sold in the United States. The source for most of this tuna is skipjack, although individual cans may contain more than one species of tuna. Albacore or "white" tuna is almost always packed in water in solid form.

NOTES: A standard of identity is used to define the species of fish that may be canned under the name "tuna" (21 CFR 161.190[a]). There is also a standard for fill-of-container of canned tuna (21 CFR 161.190[c]). These standards provide for various styles of pack, including solid pack, chunk or chunk style, flakes, and grated tuna. Provision is also made for type of packing media (water or oil), certain specified seasonings and flavorings, color designations, and methods for determining fill-of-containers (Source: http://www.cfsan.fda.gov/~dms/qa-ind4g.html).

SOURCE: Derived from US Tuna Foundation (http://www.tunafacts.org/abouttuna/index.html).

TABLE 2-4 Total Seafood: Percentage of Persons Using Food and Quantities Consumed in a Day

Statistic	All Individuals Aged 2 and Over	Age (years) and Sex			
		2–5	6–11	12–19	
		Males and Females	Males and Females	Males	Females
Number in sample	17,107	1521	2098	2244	2261
Percent of persons using in 1 day	15.9	10.2	9.9	7.9	11.2
Quantity consumed in 1 day, by users (1 ounce = 28 g)					
Mean	89.2	49.6	58.5	77.4	62.2
SEM	2.6	4.7	4.4	7.2	6.2
5th percentile	0.2	5.4	0.1	0.4	0.1
10th percentile	7.0	7.0	6.1	12.3	0.1
25th percentile	27.9	14.8	23.7	24.7	13.8
50th percentile	60.8	37.3	47.4	56.2	39.4
75th percentile	114.2	65.4	84.4	102.3	89.8
90th percentile	192.7	108.1	111.6	170.7	151.8
95th percentile	267.1	149.9	153.5	227.5	201.2
Average quantity consumed per person per day					
Mean	14.2	5.0	5.8	6.1	6.9
SEM	0.7	0.7	0.8	0.8	0.8

[a]Indicates a statistic that is potentially unreliable because of small sample size or large coefficient of variation (CVs have yet to be determined).

[b]Indicates a percentage that is greater than 0 but less than 0.05 or a mean, SEM, or percentile that is greater than 0 but less that 0.5.

SOURCE: CDC/NCHS, 1999–2002.

terns for most Americans, it is unlikely that targeted intake levels will be achieved on a population-wide scale.

Figure 2-2 provides an indication of where people are most likely to consume seafood. According to data from the 1999–2000 NHANES, about 58 percent of seafood is consumed at home or in someone else's home, 25 percent is consumed in a restaurant, and 8 percent at work or school. Only about 4 percent is consumed at a fast-food restaurant, though some at-home consumption could include seafood brought into the house from a fast-food outlet.

20–39		40–59		60 and older		Pregnant/ Lactating Women	Females, Age 15 to 45
Males	Females	Males	Females	Males	Females		
1372	1844	1345	1361	1512	1549	709	3658
16.6	17.2	19.3	19.4	17.8	18.2	19.3	16.4
110.7	83.3	112.3	82.1	101.8	76.7	97.7	81.9
7.4	6.4	7.8	6.4	7.5	5.2	15.7	5.8
3.1	0.1	4.6	0.1	2.8	3.6	0.1	0.1
8.5	4.9	16.8	1.5	16.8	11.3	0.1	3.6
29.6	26.9	49.4	27.9	41.9	25.6	37.3	24.5
72.8	58.5	90.0	55.8	83.4	56.2	60.8	55.8
151.1	95.6	137.3	118.7	118.2	105.2	119.7	98.6
257.7	172.5	237.2	178.5	220.6	166.0	268.6	174.2
292.6	268.6	294.9	252.8	352.9	192.2	306.9	262.5
18.4	14.3	21.6	15.9	18.1	14.0	18.8	13.4
1.6	1.6	1.7	1.9	1.8	0.9	3.4	1.4

Current Seafood Intake by Population Subgroups

Results from several studies indicate differences in seafood consumption among specific ethnic groups (Burger et al., 1999; Burger, 2002; Sechena et al., 2003; Sharma et al., 2003, 2004; Arnold and Middaugh, 2004; Ballew et al., 2004). Some of these population groups may have higher exposure to contaminants as a result of their seafood consumption practices. For example, they may consume more fish, compared to the general popula - tion, from waters in locations known to be contaminated. While data from studies of consumption practices are not directly comparable because of

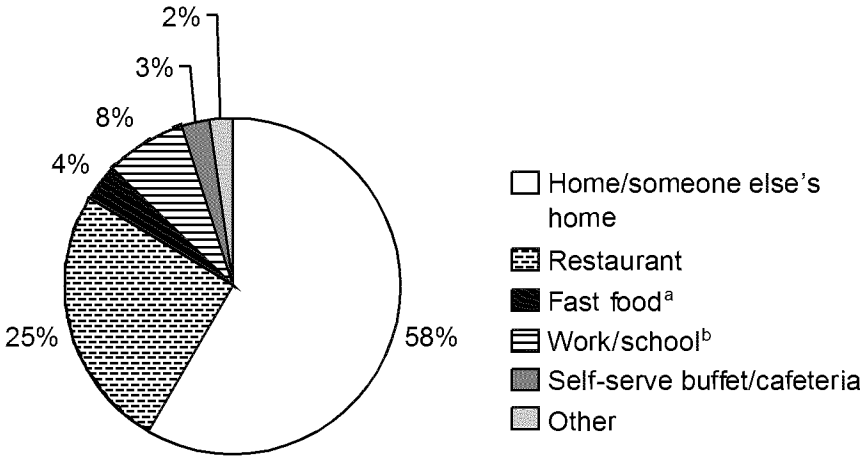

FIGURE 2-2 Distribution of seafood consumption by place it was consumed.
[a]Includes food eaten at takeout restaurant, in store, and in car.
[b]Includes food eaten by children in day care.
SOURCE: CDC/NCHS, 1999/2000.

methodological and reporting differences, they are useful for gleaning some insights into differences in consumption among different groups.

Multiethnic Cohort Study

The Multiethnic Cohort (MEC) Study is a large, population-based study designed to assess variations in specific rates of cancer occurrence among various ethnic groups and to characterize both environmental and genetic factors contributing to cancer incidence. Conducted between 1993 and 1996, the study collected comprehensive lifestyle and dietary data on the cohort (Sharma et al., 2003, 2004). The cohort reflected a range of educational levels, although cohort members were more educated than the general population.

Study participants in Hawaii and Los Angeles, California, included population samples from five self-identified ethnic groups—African Americans, Latinos, Japanese Americans, Native Hawaiians, and Whites—aged 45 to 75 years, who completed a mailed self-administered quantitative Food Frequency Questionnaire (FFQ) that was developed specifically for the study population (Sharma et al., 2004). The study objectives included providing prospective data on exposures and biomarkers thought to alter cancer risk; data collected from the questionnaires included information on dietary and other lifestyle and health practices (Kolonel et al., 2004). Table 2-5 shows

TABLE 2-5 Mean Seafood Intake Consumed Per Week Among Various Ethnic Groups, in the Multiethnic Cohort Study (1993–1996)

Ethnic Group	Mean + SD[a], Amount Consumed Per Week (ounces)
African Americans	
Men (n=11,772)	4.9±4.9
Women (n=20,130)	4.2±4.2
Latinos, born in Mexico, South or Central America	
Men (n=10,180)	4.9±5.6
Women (n=10,903)	3.5±4.9
Latinos, born in United States	
Men (n=10,613)	3.5±4.2
Women (n=11,255)	2.8±3.5
Japanese Americans	
Men (n=25,893)	7.0±6.3
Women (n=28,355)	5.6±4.9
Native Hawaiians	
Men (n=5979)	9.1±9.1
Women (n=7650)	7.7±7.7
Whites	
Men (n=21,933)	4.9±4.9
Women (n=25,303)	3.5±3.5

NOTE: The daily amounts reported in the study were converted to weekly amounts for this table.

[a]SD = Standard Deviation.

SOURCES: Derived from Sharma et al., 2003, 2004.

information collected from the MEC study on consumption of seafood by specific ethnic groups. The study reported food intakes in terms of ounces of lean meat equivalents, which for seafood can generally be thought of as ounces of cooked seafood consumed. The daily amounts reported in the study were converted to weekly amounts for Table 2-5. While these data are not representative of every ethnic group in the United States, and there is large variation in intakes among all groups; the means suggest there may be higher intakes among Native Hawaiians and Japanese Americans than among African Americans, Latinos, and Whites.

Asian American Populations

Among Asian American and Pacific Island members of the population in the contiguous United States, seafood consumption is an important aspect of cultural behavior. Self-harvesting and consuming seafood are seen as healthy activities that echo a culturally familiar lifestyle, but may also be

an economic necessity. Asian American and Pacific Island groups consume greater amounts, different types, and different parts of seafood than the general population (Sechena et al., 2003).

A large population of Laotian immigrants (Hmong) who settled in Wisconsin have been studied to determine how their fishing and seafood consumption habits differ from those of the general US population. Hutchison and Kraft (1994) found that individuals in Hmong households in Green Bay, Wisconsin, consumed an average of 30 fish meals per year compared to 18 fish meals per year consumed by Wisconsin anglers in the general population. About one-third of the fish caught were reported to come from lakes where fishing advisories warned against eating locally caught fish, suggesting that this group is at greater risk from exposure to contaminants in fish than the general population.

Some members of the Asian American population have undergone acculturation resulting in food choices that are more similar to those of the general US population than population groups from their country of origin (Kudo et al., 2000; Kim and Chan, 2004). Kudo et al. (2000) studied the eating patterns of Japanese immigrants and their US-born descendants. Their findings show dietary changes among succeeding generations of Japanese American females, and suggest that acculturation-related changes may contribute to decreased intake of many traditional foods, including fish.

American Indian/Alaskan Native and First Nations Populations

Many indigenous peoples, particularly those who live in Alaska and northern Canada, maintain a subsistence life-style and diet. The dietary practices of these populations are an important part of their self-definition, culture, health, and well-being, as well as a part of the socioeconomic structure of their communities.

A survey of coastal First Nations communities in British Columbia indicated that, although traditional dietary patterns have changed considerably since the introduction of Europeans to the Americas, seafood and other marine food sources remain an important part of the culture and nutritional resources of this population group (Mos et al., 2004). The survey showed that fishing and gathering of seafood was practiced regularly among 46 percent of respondents and that traditional methods were used 94 percent of the time. Among the types of seafood consumed by First Nations communities, salmon was the most popular; 95 percent of respondents reported consuming salmon each year and an average of 42 percent of all seafood meals consisted of salmon.

Availability of data on seafood consumption practices among Alaskan Natives and other Northern Dwellers is limited. Further, traditional foods that are consumed in Alaska vary by region, local preference, and

seasonal availability. The range of traditional foods available includes fish, marine mammals, shellfish, ascidians (sea squirts), sea cucumbers, and seaweed. Also included are nonmarine game meats, berries, and edible plants (Kuhnlein et al., 2000). Specific examples of wild-caught foods commonly consumed by Northern Dwellers include caribou meat, arctic char, Beluga (whale), muktuk, geese, whitefish, and trout (see Glossary for definitions) (Kuhnlein et al., 2000).

Muckle et al. (2001) reported that among Inuit women of childbearing age, about 80 percent consumed fish at least once per week and the average frequency of consumption of fish meals was 3.3 times per week. This population also consumed traditional products including beluga whale fat, muktuk, and seal fat, meat, and liver; their consumption of these foods increased during pregnancy.

Kuhnlein et al. (2004) report that since the introduction of nonnative foods to the Canadian Arctic at the turn of the 20th century, the use of native (traditional) foods has declined such that, among adults, only 10–36 percent of dietary energy is derived from traditional foods. Additionally, Receveur et al. (1997) found that traditional food consumption among Dene/Métis communities was associated with greater intake of iron, zinc, and potassium, and lower intake of sodium, fat, saturated fat, and sugar. Considered in conjunction with the cultural integration and importance of dietary traditions, advice to indigenous peoples to change their long-standing dietary patterns in order to reduce exposure to contaminants may not only not be beneficial, but could have deleterious health effects (Marien and Patrick, 2001).

Sport and Subsistence Fishers

The number of subsistence fishers in the United States and the amount of seafood they consume is difficult to estimate due to the challenge of identifying members of this population and a lack of data collected on them. By and large, individuals who engage in sport and subsistence fishing tend to consume more fish than the general population (Burger, 2002). Among anglers (those who crab and/or fish) in the Newark Bay Complex area of New Jersey, Blacks and Hispanics ate more fish than Whites or Asians (Burger, 2002). Similarly, Burger et al. (1999) noted that Blacks living along the Savannah River in South Carolina consumed both larger portions of seafood as well as higher total amounts compared to Whites. In that study, levels of intake were also related to education: those who did not graduate from high school ate seafood more often, consumed more total seafood, and consumed more intact fish than those with at least a high school degree.

While Alaskan Natives fish for sustenance (Ballew et al., 2004), others, e.g., the Newark Bay Complex group (Burger, 2002), angled primarily

for recreation, relaxation, and communing with nature, and more than 30 percent did not eat the crab or fish they caught. Thus, quantities obtained from fishing do not provide an accurate indicator of consumption.

FUTURE SEAFOOD SUPPLIES

Changes in Supply and Demand

The nation's seafood supply is changing in ways that are likely to have a significant impact on consumer choice in the future. Changes in amounts, types, sources, and cost of seafood are predicted to continue in the next decades due largely to increasing demand. Over the past two decades the US population has grown by about 20 percent, and consumer demand for seafood fluctuated between about 14.5 and 16.5 pounds per person (see Figure 2-1). As mentioned previously, per capita seafood consumption was 16.6 pounds in 2004 (NMFS, 2005a), which represents almost 4.7 billion pounds of seafood.

The demand for seafood in the United States now exceeds domestic supplies, and fulfilling that demand requires more dependence on international sources. Seafood on the international market currently accounts for over 75 percent of the world marine fisheries' catch, and a trend of increasing consumption is expected to continue (Watson and Pauly, 2001). The world production of edible fishery products, defined as both captured and farmed fish, reached a total of 103 million metric tons in 2003, which provided an estimated annual per capita supply of 16.3 kilograms or 35.9 pounds (live-weight equivalents) (FAO, 2004). Predictions about future world seafood supplies suggest that, at current rates of consumption, the world seafood supply will not keep pace with demand. The deficit is forecast to be 9.4 million metric tons by 2010, increasing to 10.9 million tons by 2015 (FAO, 2004). Although a recommendation to consume two 3-ounce servings of seafood per week may be beneficial to consumers (discussed in Chapter 3), if the entire population increased current consumption to meet this proposed consumption level, the supply of seafood would likely not be able to support the increased demand.

Impact of Aquaculture on Seafood Supplies

Aquaculture is one alternative that may contribute to closing the gap between diminishing seafood supplies and increasing demand. World production of seafood from farms or aquaculture operations is growing more rapidly than production of all other food-producing animals in the world (FAO, 2004). Between 1970 and 2002, the percentage of total seafood product weight provided by aquaculture production increased from 3.9 to almost

30 percent (FAO, 2004). This represents an increase of approximately one percent per year; however, that rate cannot keep pace with anticipated increases in seafood demand. Furthermore, the total aquaculture production figures can be deceiving in that the major portion of world aquaculture production involves freshwater species, e.g., carp (FAO, 2004). This fish is not a common consumer selection in most developed nations, particularly the United States.

The top ten seafood types consumed in the United States (shown in Table 2-1) are marine (or saltwater) species, although not all are wild-caught. Current seafood consumption patterns are beginning to lead to reductions in supply for some species that will influence future availability and price. For example, flatfish (e.g., flounder, sole, and halibut), among the top ten types of seafood consumed in 1990, are less prevalent today.

Aquacultured seafood (e.g., salmon, catfish, and shrimp) is now supplementing the supply for some of these seafood choices of long-standing popularity. The recent increase in per capita consumption of shrimp over tuna was in part due to the increasing supply and lower price resulting from aquaculture. Aquaculture has also contributed to the 100-fold increase in salmon consumption and introduced a new selection, tilapia, to the top ten per capita seafood consumed in 2004.

An emerging concern about aquaculture is that it is largely used for production of carnivorous species such as salmon, and the feed used is based on fish meal. The source of fish meal is considered an industrial product (wild-caught fish that is not used for human consumption) obtained from capture fisheries (FAO, 2002). Pound for pound, however, the amount of wild-caught fish needed to produce fish meal exceeds by more than two times the amount of fish produced by aquaculture for human consumption (Naylor et al., 2000).

Future Trends

Future trends in availability for the most popular seafood consumed in the United States can be estimated from comparisons of annual production over the past 10 years (Table 2-6). These estimates are based on total reported catch from 1995 through predictions for 2005.

While the NMFS and the eight regional Fishery Management Councils report that 2004 assessments of domestic stocks indicated that fishery management strategies have resulted in increases in some stocks to a sustainable yield, most of the top ten seafood choices were not among them (NMFS, 2005b). Limited availability of these popular seafood types may translate into more resource competition and higher prices.

The additional competition of recreational fishing has a further impact on seafood supplies. Coleman et al. (2004) concluded that the less-regulated

TABLE 2-6 General Trends and Predictions for the Supply and Sources of Popular Fish Consumed in the United States from 1995 through 2005

Seafood Type	Supply Trend	Domestic Supply		Imported Supply	
		Catch	Farmed	Catch	Farmed
Salmon	Increasing[e]	Limited	Limited	Increasing	Increasing
Tilapia	Increasing	Limited	Increasing	Limited	Increasing
Catfish[a]	Increasing	Limited	Limited	Increasing	Increasing
Cod	Limited[f]	Limited	N/A	Limited	Increasing
Flatfish/Soles[b]	Limited	Limited	N/A	Limited	Increasing
Tuna[c]	Limited	Limited	N/A	Limited	N/A
Haddock	Limited	Limited	N/A	N/A	N/A
Halibut	Limited	Limited	N/A	N/A	N/A
O. perch	Limited	Limited	N/A	Limited	N/A
Pollock	Limited	Limited	N/A	Limited	N/A
O. roughy	Declining[f]	N/A[g]	N/A	Limited	N/A
Rockfishes	Declining	Declining	N/A	N/A	N/A
K. mackerel[d]	Limited	Limited	N/A	N/A	N/A
Swordfish[d]	Limited	Limited	N/A	Limited	N/A
Tilefish[d]	Declining	Declining	N/A	N/A	N/A
Sharks[d]	Limited	Limited	N/A	Declining	N/A

NOTE: The listings include some of, but are not limited to, the most popular fish relative to consumption totals based on annual fishery reports and other sources.

[a]Catfish can include domestic cultured varieties as well as imported varieties.

[b]Flatfish can include flounders and sole.

[c]Tuna includes all major commercial species; tuna is also "farmed" in some countries through the capture of smaller fish, which are fed in pens.

[d]The four fish targeted by the FDA/US EPA advisory on methylmercury (FDA/US EPA, 2004).

[e]Increasing = More annual supply can be available than is currently produced either from underfished resources and/or aquaculture (existing or emerging).

[f]Supply is described as either limited or declining due to overfishing (the domestic resources are near or exceed steady state annual yield as estimated by NMFS [2005]).

[g]N/A = The resource is not available in the respective situation or data is not available per the listing.

SOURCES: FAO, 2004; NMFS, 2005a,b; SAFMC, 2005; Personal communication, W. Swingle, Gulf of Mexico Fishery Management Council, January 2006; Personal communication, G. Waugh, Deputy Executive Director, South Atlantic Fishery Management Council, January 10, 2006.

recreational fishery is exerting a large impact on certain popular seafood selections. They reported that in 2002, the recreational catch of fish "populations of concern" (i.e., popular types that were at risk for overfishing) accounted for 64, 38, 59, and 12 percent of the catch in the Gulf of Mexico, South Atlantic, Pacific, and Northeastern coastal waters, respectively. Some of these recreationally caught and consumed types, e.g., king mackerel,

have been identified in advisories as fish that pregnant women should not consume. In the Gulf of Mexico, the regional fishery management plans allocate 68 percent of the king mackerel harvest to recreational fishermen (GMFMC, 2006).

Table 2-6 shows that several popular species are overfished and supplies are declining. Among capture fisheries worldwide, 28 percent of fish stocks have been estimated to be depleted or overexploited (FAO, 2002). In the United States, over 18 percent of the 236 fish stocks or stock complexes with known overfishing status have a mortality rate that exceeds the overfishing threshold (i.e., subject to overfishing) (NMFS, 2005b). Supply predictions for shark (Baum et al., 2003), tilefish, king mackerel, and swordfish (identified in the joint FDA/US EPA methylmercury advisory) suggest that they will likely decrease. In addition, changes in the supply of other wild-caught seafood will also influence seafood selections for all segments of the population in the future.

NUTRIENT PROFILES OF SEAFOOD COMPARED TO OTHER FOODS IN THE DIET

Foods with similar nutrient profiles are often grouped together for the purpose of making dietary recommendations. Seafood is grouped with meats, poultry, eggs, nuts, legumes, and seeds as major contributors (supplying >50 percent) of protein, niacin, zinc, and vitamin B6 to the diet. These foods are also substantial contributors (supplying >10 percent) of vitamins E and B12, thiamin, riboflavin, phosphorus, magnesium, iron, copper, potassium, and linoleic acid. Among these foods, however, higher levels of selenium and the omega-3 fatty acids EPA and DHA and generally lower levels of saturated fats are unique to seafood. Although EPA and DHA are found in other protein-rich foods (i.e., poultry and eggs), fish that are high in EPA/DHA (e.g., salmon, lake trout, and white [albacore] tuna) have the highest concentration per serving among food sources. Table 2-7 provides a comparison of the availability of some macro- and micronutrients, including the omega-3 fatty acids EPA (20:5 n-3) and DHA (22:6 n-3) in three types of seafood, as well as chicken, beef, and eggs, and the alpha-linolenic acid (ALA; 18:3 n-3) in walnuts.

EPA and DHA

An important reason for choosing seafood over other protein food sources is that it is a primary source of the omega-3 fatty acids EPA and DHA. The benefits of these two fatty acids are described in detail in Chapter 3. The following discussion provides information about sources and consumption patterns of EPA/DHA.

TABLE 2-7 Nutrients in Selected Seafoods and Other Comparable Foods

Food	Content per 100 g		
	Energy (kcal)	Protein (g)	Total Fat (g)
FISH			
Tuna, canned, light, packed in water	116	25.51	0.82
Tuna, canned, white, packed in water	128	23.62	2.97
Shrimp, mixed species, cooked, moist heat	99	20.91	1.08
Salmon, Atlantic, farmed, cooked, dry heat	206	22.10	12.35
Pollock, Atlantic, cooked, dry heat	118	24.92	1.26
Catfish, channel, farmed, cooked, dry heat	152	18.72	8.02
Cod, Atlantic, cooked, dry heat	105	22.83	0.86
Crab, blue, cooked, moist heat	102	20.20	1.77
Halibut, Atlantic and Pacific, cooked, dry heat	140	26.69	2.94
BEEF			
Ground beef, 80% lean, patty, cooked, broiled	271	25.75	17.82
Eye of round roast, all grades, trimmed to 1/8" fat, cooked	208	28.31	9.65
Top sirloin, all grades, trimmed to 1/8" fat, cooked, broiled	243	26.96	14.23
PORK			
Cured ham, boneless, regular, roasted	178	22.62	9.02
Pork loin, center rib, boneless, cooked, roasted	252	26.99	15.15
Ground fresh pork, cooked	297	25.69	20.77
POULTRY			
Chicken breast, meat and skin, cooked, roasted [b]	197	29.80	7.78
Chicken breast, meat only, cooked, roasted [b]	165	31.02	3.57
Turkey, meat and skin, cooked, roasted	208	28.10	9.73
Turkey, ground, cooked	235	27.36	13.15
SAUSAGES AND LUNCHEON MEATS			
Frankfurter, meat	290	10.26	25.76
Frankfurter, beef	330	11.24	29.57
Turkey roll, light meat	147	18.70	7.22
Bologna, beef and pork	308	15.20	24.59
OTHER			
Egg, poached [b]	147	12.53	9.90
Egg, omega [c]	125	10.00	10.00
Walnuts, English	654	15.23	65.21
Seeds, flaxseed	534	18.29	42.16

[a] Total 18:3 fatty acid.

[b] EPA/DHA levels in chicken and egg are based on existing published data; changes in the use of fishmeal in feed sources may impact levels detected in the future.

[c] Derived from Sindelar et al., 2004.

—No data available.

SOURCE: USDA National Nutrient Database for Standard Reference, Release 18 (unless otherwise specified).

SFA (g)	EPA (g)	DHA (g)	ALA (g)	Ca (mg)	Fe (mg)	Zn (mg)	Se (µg)	B-6 (mg)
0.234	0.047	0.223	0.002[a]	11	1.53	0.77	80.4	0.350
0.792	0.233	0.629	0.071[a]	14	0.97	0.48	65.7	0.217
0.289	0.171	0.144	0.012[a]	39	3.09	1.56	39.6	0.127
2.504	0.690	1.457	0.113[a]	15	0.34	0.43	41.4	0.647
0.170	0.091	0.451	—	77	0.59	0.60	46.8	0.331
1.789	0.049	0.128	0.082[a]	9	0.82	1.05	14.5	0.163
0.168	0.004	0.154	0.001[a]	14	0.49	0.58	37.6	0.283
0.228	0.243	0.231	0.021[a]	104	0.91	4.22	40.2	0.180
0.417	0.091	0.374	0.083[a]	60	1.07	0.53	46.8	0.397
6.766	—	—	0.050	24	2.48	6.25	21.5	0.367
3.664	—	—	0.093[a]	7	2.29	4.70	28.7	0.372
5.603	—	—	0.127[a]	20	1.73	4.87	29.2	0.564
3.120	—	—	0.240[a]	8	1.34	2.47	19.8	0.310
5.350	—	—	0.030[a]	6	0.93	2.64	40.3	0.363
7.720	—	—	0.070[a]	22	1.29	3.21	35.4	0.391
2.190	0.010	0.030	0.060[a]	14	1.07	1.02	24.7	0.560
1.010	0.010	0.020	0.030[a]	15	1.04	1.00	27.6	0.600
2.840	—	0.040	0.110[a]	26	1.79	2.96	32.9	0.410
3.390	—	0.030	0.150[a]	25	1.93	2.86	37.2	0.390
7.667	—	—	0.146[a]	99	1.09	1.20	12.5	0.166
11.688	—	—	0.176[a]	14	1.51	2.46	8.2	0.089
2.020	—	0.020	0.090[a]	40	1.28	1.56	22.3	0.320
9.301	—	—	0.055[a]	85	1.21	2.30	24.6	0.297
3.087	0.004	0.037	0.033[a]	53	1.83	1.10	31.6	0.142
2.500	—	0.170	0.420	—	—	—	—	—
6.126	—	—	9.080[a]	98	2.91	3.09	4.9	0.537
3.663	—	—	22.813[a]	255	5.73	4.34	25.4	0.473

Sources of EPA and DHA

Seafood is the primary source for EPA and DHA in human diets. Estimated amounts of EPA and DHA in the top seafood types consumed are shown in Table 2-8. The figures suggest that, other than salmon, the most frequently consumed types of fish are not particularly rich sources of these fatty acids.

The fatty acid concentration of farmed fish reflects the composition of the diets they are fed (Bell et al., 2003). Fish, like mammals, have a limited ability to deposit EPA and DHA in their tissues even when they are fed diets high in ALA (Tocher et al., 2003). Thus, farmed salmon need to be fed a source of EPA and DHA (e.g., fish oil) to have a fatty acid profile similar to that of wild salmon. Feeding diets that are high in fish oil for a period prior to harvest elevates levels of EPA and DHA in farmed salmon previously fed vegetable oils during part of their growing period (Bell et al., 2003).

TABLE 2-8 Mean Levels of EPA and DHA in the Top 10 Seafood Types Consumed in the United States

Seafood (type)[a]	# Data Points	Standard Error	EPA Content (g/100 g)	DHA Content (g/100 g)	Total n-3 Content (g/100 g)
Shrimp	11	N/A[b]	0.17	0.14	0.31
Light tuna	5	N/A	0.05	0.22	0.27
Salmon	2	N/A	0.69	1.46	2.15
Pollock	0[c]	N/A	0.09	0.45	0.54
Catfish	3	N/A	0.05	0.13	0.18
Tilapia	2	N/A	0.00	0.11	0.11
Crab	12 (EPA) 10 (DHA)	0.021 (EPA) 0.008 (DHA)	0.30	0.12	0.42
Cod	0[c]	N/A	0.00	0.15	0.15
Clams	0[c]	N/A	0.14	0.15	0.29
Flatfish	11	32.5 (EPA) 22.3 (DHA)	0.24	0.26	0.50

[a]Shrimp = Mixed, cooked, moist heat; Light tuna = light, canned in water, drained; Salmon = Atlantic, farmed, cooked; Pollock = Atlantic, cooked, dry heat; Catfish = Channel, farmed, cooked, dry heat; Tilapia = Cooked, dry heat; Crab = Alaska king, cooked, moist heat; Cod = Atlantic, cooked, dry heat; Clams = Mixed, cooked, moist heat; Flatfish = Flounder and sole species, cooked, dry heat.

[b]N/A means that the values are not available.

[c]As reported in USDA Nutrient Database Release 18 (http://www.nal.usda.gov/fnic/foodcomp/Data/SR18/sr18.html). Zeroes indicate that value was not derived analytically but was either calculated by difference or imputed from the value for some other similar food(s).

SOURCES: National Fisheries Institute (http://www.aboutseafood.com/media/top_10.cfm) and USDA Nutrient Database Release 18 (http://www.nal.usda.gov/fnic/foodcomp/Data/SR18/sr18.html).

As discussed in Chapter 1, the *Dietary Guidelines Advisory Committee Report* (DGAC, 2005) recommends that adults consume two portions (each 4 ounces raw/3 ounces cooked) of seafood per week. Following this recommendation would provide the consumer with a range of intake levels from 60 mg to 700 mg of EPA and DHA combined per day, depending on the type of seafood consumed.

Table 2-9 shows mean dietary intake levels of EPA, DHA, and EPA and DHA combined, for several sex/age groups from the 1999–2002 NHANES. Mean intake levels for the total population are estimated to be 35 mg of EPA and 68 mg of DHA per day. Although adults had greater intakes than children, and men greater intakes than women, none of the sex/age groups shown had average intakes of even 200 mg per day of EPA and DHA combined.

Consumption of High Compared to Low EPA/DHA Content Seafood

An analysis of NHANES data classified all seafood types as either high (> 500 milligrams per 3-ounce serving) or low (< 500 milligrams per 3-ounce serving) in EPA and DHA combined (DGAC, 2005). High EPA/DHA seafood includes anchovy, mackerel, pompano, salmon, sardines, sea bass, swordfish, and trout. Low EPA/DHA types include carp, catfish, clams, conches, cod, crabs, croaker, flounder, frogs, haddock, halibut, lobster, mullet, octopuses/squid, oysters, perch, pike, pollock, porgy, scallops, shrimp, snapper, and whiting.

In the NHANES survey, tuna was considered separately, because although there are both high- and low-EPA/DHA varieties of tuna, respondents usually cannot distinguish between them. Therefore, 75 percent of the tuna consumed was assigned to the low EPA/DHA group and the remainder to the high EPA/DHA group in accordance with USDA figures (DGAC, 2005). Figure 2-3 shows that the greatest percentage of seafood consumed is low in EPA/DHA, and that salmon, white tuna, sea bass, and trout are the most commonly consumed types of seafood high in EPA/DHA.

Another way to consider sources of EPA/DHA is to examine which foods contribute the most to the population's intake, a method that takes into account not only each food's fatty acid content but also in what quantities it is consumed. Tables 2-10 and 2-11 show the foods contributing the most to EPA and DHA intakes, respectively, according to data from the NHANES 1999–2002. Not surprisingly, various seafood types are among the major contributors of both fatty acids. What might not be expected, however, is that chicken and eggs contributed measurable amounts to EPA intake over this time period. Soups, while only contributing 1.8 percent of the EPA, are a curious addition to the table. These include not only fish chowders, but soups made from chickens that have been fed fishmeal. Whether chicken

TABLE 2-9 Dietary Intake of Linolenic Fatty Acid, Eicosapentaenoic Fatty Acid (EPA), Docosahexaenoic Fatty Acid (DHA), and EPA and DHA Combined

Statistic	All Individuals Aged 2 and Over	Age (years) and Sex			
		2–5	6–11	12–19	
		Males and Females	Males and Females	Males	Females
Number in sample	17,107	1521	2098	2244	2261
	g				
Linolenic fatty acid					
Mean	1.41	0.90	1.16	1.49	1.23
SEM	0.01	0.02	0.03	0.04	0.03
	mg				
Eicosapentaenoic fatty acid (EPA)					
Mean	35.26	11.94	14.16	16.91	16.78
SEM	1.99	2.10	1.74	1.91	1.68
Docosahexaenoic fatty acid (DHA)					
Mean	67.98	27.99	37.72	43.75	39.89
SEM	2.66	3.18	4.09	3.12	3.23
EPA and DHA combined					
Mean	103.25	39.93	51.87	60.67	56.66
SEM	4.53	5.21	5.59	4.64	4.68

SOURCE: CDC/NCHS, 1999–2002.

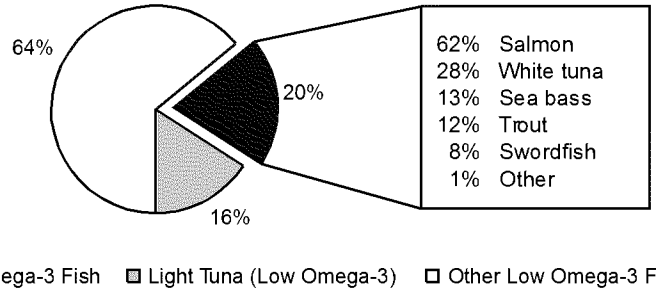

FIGURE 2-3 Consumption estimates, as a percentage of total seafood consumed, by EPA/DHA content classification. High-EPA/DHA seafood is further delineated by type; white (albacore) tuna is high in EPA/DHA but light (e.g., skipjack) tuna is not.
SOURCE: DGAC, 2005.

	20–39		40–59		60 and older		Pregnant/ Lactating	Females, Aged 15 to 45
	Males	Females	Males	Females	Males	Females	Women	Years
	1372	1844	1345	1361	1512	1549	709	3658
	1.74	1.33	1.75	1.33	1.45	1.18	1.47	1.32
	0.04	0.04	0.04	0.04	0.03	0.02	0.06	0.03
	42.83	32.66	56.42	42.99	43.17	36.43	40.13	34.09
	4.23	2.73	5.14	7.56	4.60	3.19	8.80	4.69
	82.43	63.01	108.92	72.55	78.14	64.88	73.19	62.11
	6.22	5.15	7.83	7.82	5.89	4.01	10.54	4.93
	125.26	95.67	165.33	115.54	121.31	101.31	113.32	96.19
	10.19	7.66	12.59	14.96	10.27	7.11	18.72	9.33

and egg products will continue to contribute significant amounts of DHA is uncertain because of changes in feed composition aimed at reducing amount of fishmeal used in animal feeds (Barlow, 2001).

As with farmed fish, feeding practices used in the poultry and egg industries may affect the content of EPA/DHA in these foods. Poultry feeds are predominantly vegetable- and grain-based, supplemented with animal and grain by-products (IOM, 2003), with cost driving the feed formulation. Fat sources used in poultry feed formulations can include animal fat, vegetable fat or oil, or feed-grade fat products (Hulan et al., 1989; Ratnayake and Ackman, 1989; Cantor, 1999; Gonzalez-Esquerra and Leeson, 2000). The feed ingredients most frequently used to increase the long-chain polyunsaturated fatty acid (LCPUFA) content of poultry meat include fish oil, flaxseed oil, and rapeseed (canola) oil (Komprda et al., 2005). The amount of fish meal used in a formulation has typically been about 1 percent of the total ingredients (IOM, 2003). Recent changes in fat sources used in poultry feed resulting in a lower fish meal content (Barlow, 2001) suggest a probable

TABLE 2-10 Food Sources of EPA Among the US Population, Aged 2 Years and Older, 1999–2002

Food Group[a]	Percent of EPA	Cumulative Percent of EPA
Salmon	19.8	19.8
Shrimp	18.8	38.6
Chicken[b]	8.9	47.5
Crab	5.6	53.1
Trout	3.6	56.7
Tuna	3.2	59.9
Sardines	2.1	62.0
Catfish	2.0	64.0
Soups	1.8	65.8
Cod	1.6	67.4
Eggs	1.5	68.9
Fish, mixed types	1.5	70.4
Flounder	1.2	71.6
Other fish[c]	20.9	92.5

NOTE: Species not shown contributed <1 percent each.

[a]Includes mixed dishes composed mainly of this item.

[b]New data forthcoming show most nutrient levels comparable to earlier sample, but EPA/DHA levels as undetectable.

[c]Includes types not specified by respondent and types other than those listed elsewhere in table.

SOURCE: CDC/NCHS, 1999–2002.

decrease in detectable EPA/DHA levels in poultry and egg products. New forthcoming data on chicken and eggs show levels of most nutrients are comparable to earlier samples, but EPA/DHA levels as undetectable.

When egg-producing hens are fed diets enriched with EPA and DHA, their egg lipid content reflects their diet composition (Scheideler and Fron - ing, 1996; Van Elswyk, 1997; Cantor, 1999; Bean and Leeson, 2003). Scheideler and Froening (1996) showed that the DHA content of eggs could be increased by about 3.5 times over that of unmodified eggs by feeding hens diets containing 5 percent whole flaxseed (2.8 times for a diet containing 5 percent ground flaxseed) compared to unmodified diets for control hens, indicating that some conversion of ALA to DHA occurs in the hen. The ALA content of the eggs increased nearly eightfold under the same conditions. Similarly, hens fed a diet with 2.5 percent dried algae meal high in DHA produced eggs with about 150 mg DHA per egg (Herber and Van Elswyk, 1996), similar to the level produced by feeding 1.5 percent fish oil.

Non-Animal Sources of Omega-3 Fatty Acids It is important for consumers to understand that there are different sources of omega-3 fatty acids. EPA and DHA are not endogenously synthesized from saturated, monounsatu -

TABLE 2-11 Food Sources of DHA Among the US Population, Aged 2 and Older, 1999–2002.

Food Group[a]	Percent of DHA	Cumulative Percent of DHA
Chicken[b]	15.6	15.6
Salmon	14.3	30.0
Eggs	9.4	39.4
Shrimp	8.6	48.0
Tuna	7.6	55.6
Trout	4.9	60.5
Catfish	3.1	63.6
Crab	2.9	66.5
Cod	1.6	68.1
Poultry, cold cuts/ground	1.3	69.4
Sardines	1.3	70.7
Fish, mixed types[c]	1.1	71.8
Turkey	1.0	72.8
Other fish	16.9	89.7

NOTE: Species not shown contributed < 1 percent each.

[a]Includes mixed dishes composed mainly of this item.

[b]New data forthcoming show most nutrient levels comparable to earlier sample, but EPA/DHA levels as undetectable.

[c]Includes types not specified by respondent and types other than those listed elsewhere in table.

SOURCE: CDC/NCHS, 1999–2002.

rated, or omega-6 fatty acids; they can only be made from the precursor omega-3 fatty acid ALA. Some current recommendations include the use of plant sources, such as walnuts and flaxseed oil, to obtain sufficient amounts of EPA and DHA in the diet (ADA, 2003). This suggestion is based on the observation that some vegetable oils contain significant amounts of ALA, and thus could be used as an alternative to direct consumption of EPA and DHA (refer to Supplemental Information, Appendix A for detailed information). However, as mentioned previously, humans do not convert EPA or DHA from ALA at rates high enough to reach recommended intake levels (Pawlosky et al., 2001). Furthermore, based on in vivo isotope studies, the rates of conversion differ between young men and women (Burdge et al., 2002; Burdge and Wootton, 2002), and between nonpregnant, pregnant, lactating and nonpregnant, and nonmenopausal women (Burdge and Wootton, 2002). Additionally, the extent to which ALA is utilized for energy rather than converted into EPA and DHA is likely driven by both the physiologic requirements for these fatty acids and by the quantity available in the diet (Burdge et al., 2002). For example, if the physiologic requirement for EPA is high, e.g., during pregnancy and lactation, and other energy needs are being met, there is likely to be more efficient utilization of ALA as a

precursor source for EPA in women. On the other hand, an adult male who is not at risk for heart disease and whose energy needs are greater than his intake of calories from other sources would preferentially utilize ALA as an energy source rather than as a source of omega-3 fatty acids.

Production of long-chain polyunsaturated fatty acids from microorganisms, including lower fungi, bacteria, and marine microalgae, appears to be a promising source of omega-3 fatty acids, especially DHA (Cohen et al., 1995). The organisms *Schizochytrium* sp. and *Crypthecodinium cohnii* are currently used in commercial production of DHA. Sijtsma and de Swaaf (2004) have estimated that 50 large bioreactors could produce up to 10 percent of the quantity of DHA currently obtained from global production of fish oil.

The production of EPA and DHA in mustard seed has recently been achieved by application of genetic engineering techniques by Wu et al. (2005). The oil in the engineered mustard seeds contained 15 percent EPA and 1.5 percent DHA. The investigators were optimistic that a higher content of DHA could be achieved in further work. Therefore, although fish are presently the principal source of EPA and DHA available for human diets, there are several alternative sources available and more in development.

Dietary Supplements as Sources of EPA and DHA

The use of fish-oil supplements has increased over the past three decades, presumably as a result of publicity regarding the many studies showing a relationship between fish-oil supplementation and reduced risk for heart disease (e.g., Blonk et al., 1990; Reis et al., 1990; Bairati et al., 1992; Bucher et al., 2002; Marchioli et al., 2002; Vanschoonbeek et al., 2003). In 1998, Nutrition Business International (1998) forecast a market growth of 14–16 percent annually for fish-oil supplements compared to the industry's supplement average of 13 percent.

Fish oils used as food ingredients and dietary supplements are derived from a variety of different fish and are processed in different ways; consequently, their fatty acid profiles differ, especially in their content of the principal omega-3 fatty acids, EPA and DHA. The EPA and DHA content of some typical fish-oil supplements is shown in Table 2-12. The first five entries in this table are fish oils that have been determined to be generally recognized as safe (GRAS) for addition to foods and for which notices were submitted to the Food and Drug Administration (FDA). [1] Some fish oils are specially processed to increase the concentration of EPA and DHA, but unmodified fish oils contain from about 10 to 30 percent of these fatty acids, respectively.

[1] Information on sample number and variability not available.

TABLE 2-12 EPA and DHA Content of Fish-Oil Supplements

Fish Oil	Manufacturer	EPA Content (g/100 g)	DHA Content (g/100 g)	Data Source[a]
Small Planktivorous Pelagic Fish Body Oil (SPPFBO)	Jedwards	18.0	12.0	GRAS Notice #102, 2002
Fish Oil Concentrate	Unilever	20.0	18.0	GRAS Notice #105, 2002
Tuna Oil	Clover	6.0	26.5	GRAS Notice #109, 2002
18/12 Triglycerides	Ocean Nutrition Canada (ONC)	18.5	11.8	GRAS Notice #138, 2003
Salmon Oil	Jedwards	8.0	12.0	GRAS Notice #146, 2004
Menhaden Oil	Unspecified	13.1	6.7	FDA, 1997 (Federal Register 62, No. 108, Rules and Regulations)
Herring Oil	Unspecified	6.3	4.2	USDA Nutrient Database for Standard Reference, Release 18
Salmon Oil	Unspecified	13.0	18.2	USDA Nutrient Database for Standard Reference, Release 18
Sardine Oil	Unspecified	10.1	10.7	USDA Nutrient Database for Standard Reference, Release 18

[a]Information on sample number and variability not available.

A variety of fatty acids other than EPA and DHA are also found in fish oils. While these oils are generally lower in saturated fatty acids than other animal-derived fats and oils, they do contain about 20–25 percent saturated fatty acids by weight, as well as from about 20 to about 55 percent mono - unsaturated fatty acids (Table 2-12).

CONTAMINANTS OF CONCERN IN SEAFOOD

Methylmercury

Methylmercury is an environmental contaminant found in nearly all seafood. It is a potent neurotoxin (ATSDR, 1999; NRC, 2000; Satoh, 2003). Its origin and metabolism are discussed in a recent NRC report (NRC, 2000). Table 2-13 presents the average mercury concentrations in

TABLE 2-13 Methylmercury Concentrations in Seafood

Seafood Type	Mercury Concentration (ppm)[a] Mean	Median	Min	Max	*n*	Source[b]	Market[c] (%)
Anchovies	0.04	NA	ND	0.34	40	NMFS 1978	0.5
Bass (saltwater)[d]	0.27	0.15	0.06	0.96	35	FDA 1990–03	0.6
Bluefish	0.31	0.30	0.14	0.63	22	FDA 2002–03	0.1
Buffalo fish	0.19	0.14	0.05	0.43	4	FDA 1990–02	0.0
Butterfish	0.06	NA	ND	0.36	89	NMFS 1978	0.1
Carp	0.14	0.14	0.01	0.27	2	FDA 1990–02	0.0
Catfish	0.05	ND	ND	0.31	22	FDA 1990–02	4.8
Clams	ND	ND	ND	ND	6	FDA 1990–02	1.7
Cod	0.11	0.10	ND	0.42	20	FDA 1990–03	4.7
Crab[e]	0.06	ND	ND	0.61	59	FDA 1990–02	4.7
Crawfish	0.03	0.03	ND	0.05	21	FDA 2002–03	0.6
Croaker (Atlantic)	0.05	0.05	0.01	0.10	21	FDA 1990–03	0.3
Croaker white (Pacific)	0.29	0.28	0.18	0.41	15	FDA 1990–03	0.0
Flatfish[f]	0.05	0.04	ND	0.18	22	FDA 1990–02	3.6
Grouper	0.55	0.44	0.07	1.21	22	FDA 2002–03	0.2
Haddock	0.03	0.04	ND	0.04	4	FDA 1990–02	0.6
Hake	0.01	ND	ND	0.05	9	FDA 1990–02	0.3
Halibut	0.26	0.20	ND	1.52	32	FDA 1990–02	0.9
Herring	0.04	NA	ND	0.14	38	NMFS 1978	2.5
Jacksmelt	0.11	0.06	0.04	0.50	16	FDA 1990–02	0.0
Lobster (Northern/American)	0.31	NA	0.05	1.31	88	NMFS 1978	1.3
Lobster (spiny)	0.09	0.14	ND	0.27	9	FDA 1990–02	0.8
Mackerel, Atlantic (N. Atlantic)	0.05	NA	0.02	0.16	80	NMFS 1978	0.3
Mackerel, chub (Pacific)	0.09	NA	0.03	0.19	30	NMFS 1978	0.2
Mackerel, king	0.73	NA	0.23	1.67	213	Gulf 2000	0.1
Mackerel, Spanish (Gulf of Mexico)	0.45	NA	0.07	1.56	66	NMFS 1978	0.0
Mackerel, Spanish (S. Atlantic)	0.18	NA	0.05	0.73	43	NMFS 1978	0.0
Marlin	0.49	0.39	0.10	0.92	16	FDA 1990–02	0.0
Monkfish	0.18	NA	0.02	1.02	81	NMFS 1978	0.4
Mullet	0.05	NA	ND	0.13	191	NMFS 1978	0.2
Orange roughy	0.54	0.56	0.30	0.80	26	FDA 1990–03	0.2
Oysters	ND	ND	ND	0.25	34	FDA 1990–02	0.8
Perch (freshwater)	0.14	0.15	ND	0.31	5	FDA 1990–02	0.0
Perch ocean	ND	ND	ND	0.03	6	FDA 1990–02	0.5
Pickerel	ND	ND	ND	0.06	4	FDA 1990–02	0.1
Pollock	0.06	ND	ND	0.78	37	FDA 1990–02	11.1
Sablefish	0.22	NA	ND	0.7	102	NMFS 1978	0.3
Salmon (canned)	ND	ND	ND	ND	23	FDA 1990–02	0.9
Salmon (fresh/frozen)	0.01	ND	ND	0.19	34	FDA 1990–02	7.9
Sardine	0.02	0.01	ND	0.04	22	FDA 2002–03	1.2
Scallops	0.05	NA	ND	0.22	66	NMFS 1978	0.8
Scorpion fish	0.29	NA	0.02	1.35	78	NMFS 1978	0.9

TABLE 2-13 Continued

Seafood Type	Mercury Concentration (ppm)[a] Mean	Median	Min	Max	*n*	Source[b]	Market[c] (%)
Shad (American)	0.07	NA	ND	0.22	59	NMFS 1978	0.0
Shark[g]	0.99	0.83	ND	4.54	351	FDA 1990–02	0.1
Sheepshead	0.13	NA	0.02	0.63	59	NMFS 1978	0.0
Shrimp	ND	ND	ND	0.05	24	FDA 1990–02	15.1
Skate	0.14	NA	0.04	0.36	56	NMFS 1978	0.3
Snapper	0.19	0.12	ND	1.37	25	FDA 2002–03	0.5
Squid	0.07	NA	ND	0.40	200	NMFS 1978	1.0
Swordfish	0.97	0.86	0.10	3.22	605	FDA 1990–02	0.4
Tilapia	0.01	ND	ND	0.07	9	FDA 1990–02	1.9
Tilefish (Atlantic)	0.15	0.10	0.06	0.53	17	FDA 2002–03	0.0
Tilefish (Gulf of Mexico)	1.45	NA	0.65	3.73	60	NMFS 1978	0.0
Trout (freshwater)	0.03	0.02	ND	0.13	17	FDA 2002–03	0.7
Tuna (canned, albacore)	0.35	0.34	ND	0.85	179	FDA 1990–03	5.3
Tuna (canned, light)	0.12	0.08	ND	0.85	131	FDA 1990–03	13.4
Tuna (fresh/frozen)	0.38	0.30	ND	1.30	131	FDA 1990–02	1.8
Weakfish (sea trout)	0.25	0.16	ND	0.74	27	FDA 1990–03	0.1
Whitefish	0.07	0.05	ND	0.31	25	FDA 1990–03	0.2
Whiting	ND	ND	ND	ND	2	FDA 1990–02	4.1

[a]Mercury was measured as total mercury and/or methylmercury. ND—mercury concentration below the level of detection (LOD = 0.01 ppm). NA—data not available.

[b]Source of data: FDA Surveys 1990–2003 (FDA, 2004), *National Marine Fisheries Service Survey of Trace Elements in the Fishery Resource* (Hall et al., 1978), *A Survey of the Occurrence of Mercury in the Fishery Resources of the Gulf of Mexico* (Ache et al., 2000).

[c]Market share calculation based on 2001 National Marine Fisheries Service published landings data (NMFS, 2002).

[d]Includes sea bass/striped bass/rockfish.

[e]Includes blue, king, and snow crab.

[f]Includes flounder, plaice, sole.

[g]Includes multiple species of shark.

SOURCE: Derived from *Regulatory Toxicology and Pharmacology* 40(3), Carrington CD, Montwill B, Bolger PM. An intervention analysis for the reduction of exposure to methylmercury from the consumption of seafood by women of child-bearing age, 274–280, 2004, with permission from Elsevier.

species of fish and shellfish reported consumed by women in the 1999–2000 NHANES (Carrington et al., 2004). Mercury levels in fish do not appear to have changed appreciably over recent decades, although the data are limited (US EPA, 1997).

Persistent Organic Pollutants

Persistent organic pollutants (POPs) are lipophilic contaminant compounds and tend to bioaccumulate up the food chain. They include such

substances as dioxins, dioxin-like compounds (DLCs), and polychlorinated biphenyls (PCBs), including those with dioxin-like activity. Dioxins, dioxin-like compounds (including PCBs with dioxin-like activity) (DLCs) and PCBs are the most frequently occuring POPs in seafood. A variety of lipophilic pesticide contaminants have been found in fish from the Great Lakes (Giesy et al., 1994; Anderson et al., 1998; Chernyak et al., 2005) and both farmed and wild-caught salmon from European waters (Food Safety Authority of Ireland, 2002; Foran et al., 2004; Hites et al., 2004b; Hamilton et al., 2005). Among these contaminants, aldrin and dieldrin have been found in amounts exceeding 1 ∝g/kg body weight in the Great Lakes (Anderson et al., 1998; Cole et al., 2002; Schmitt et al., 1999). The Salton Sea, a large manmade lake in California, was reported to have high levels of some or - ganochlorine compounds (OCs) in 2001 (Sapozhnikova et al., 2004). The toxicity of these compounds varies widely, and the implications for human health remain controversial.

Several investigators have found that levels of many POPs are higher in commercially available farmed fish than in wild-caught fish (Easton et al., 2002; Hites et al., 2004a,b; Foran et al., 2005). Van Leeuwen and de Boer (2004) tabulated contaminant data for PCBs, OCspolychlorinated dibenzo-*p*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), dioxin-like PCBs, polybrominated diphenyl ethers (PBDEs), and others. Table 2-14 shows estimated DLC levels in seafood from the FDA Total Diet Study Market Basket Survey. The reported values differ from 2001 through 2004, in part because of changes in analytical detection techniques.

Impact of Toxicants on Selenium Status

Several environmental organic toxicants have a direct or indirect impact on antioxidant status or oxidative stress of various organisms (Halliwell and Gutteridge, 1999). Therefore, studies have examined what influences such compounds may have on selenoproteins involved in modulation of oxidative stress.

Dioxin

2,3,7,8-Tetrachlorodibenzo-*p*-dioxin (TCDD) inhibits hepatic selenium-dependent but not selenium-independent glutathione peroxidase in hamsters (Hassan et al., 1983). Supplemental dietary selenium will partially protect against TCDD toxicity in rats (Hassan et al., 1985).

Polychlorinated Biphenyls

PCB exposure causes significant increases in hepatic levels of lipid

TABLE 2-14 Total Diet Study Analyses of Dioxin-like Compounds in Seafood, 2001–2004

	PCDD[a] TEQ[b], Pg/g[c], ND = LOD/2[d] (by year reported)			
Seafood Type	2001	2002	2003	2004
Tuna, canned in oil	0.0057	0.0050	N/A	N/A
Tuna, canned in water	N/A	N/A	0.0110	0.0182
Tuna noodle casserole	0.0334	0.0318	0.0826	0.0159
Fish sticks, frozen	0.0335	0.0667	0.0126	0.0053
Shrimp, boiled	0.0597	0.0834	0.0032	0.0151
Salmon, fillets	0.3257	0.1504	0.2585	0.0795
Fish sandwich, fast-food	0.0138	0.0059	0.0152	0.0078
Clam chowder, canned	0.0054	0.0169	0.0096	0.0154
Catfish, cooked in oil	N/A	N/A	0.2971	0.2055

[a]PCDD = Polychlorinated dibenzo- *p*-dioxin.

[b]TEQ = Toxicity Equivalents (see Chapter 4 for explanation).

[c]Pg/g = Picograms of contaminant per gram of food (see Chapter 4 for explanation).

[d]ND = LOD/2 refers to the non-detect limit expressed as the limit of detection×0.5.

SOURCE: USDA Total Diet Study (http://www.cfsan.fda.gov/ ~lrd/dioxdata.html).

peroxidation, glutathione, glutathione reductase, glucose-6-phosphate de - hydrogenase, and glutathione S-transferase in rats fed diets low in selenium but not in rats fed adequate selenium (Chow and Gairola, 1981; Chow et al., 1981). Thus, dietary selenium deprivation renders rats more sensitive to PCB effects.

FINDINGS

1. Seafood is a primary source of the omega-3 long-chain polyunsatu - rated fatty acids (LCPUFA) eicosapentaenoic acid (EPA) and docosahexae - noic acid (DHA), but not all seafood is rich in these fatty acids.

2. Relative to other foods in the meat, poultry, fish, and egg group, fish is generally lower in saturated fatty acids and higher in EPA, DHA, and selenium than most other choices.

3. Seafood may also contain chemical contaminants (e.g., methylmer - cury, POPs). While there are data on the methylmercury content of many types of seafood, there are virtually no data on other contaminants and pollutants.

4. Average quantities of seafood consumed by the general US popula - tion, and by several specific population groups, are below levels suggested by

many authoritative groups including levels recommended by the American Heart Association for cardiovascular disease prevention.

5. Average quantities of EPA and DHA consumed by the general US population, and by several specific population groups, are also below levels recommended by many authoritative groups.

6. For many ethnic and geographic subgroups, there are insufficient data to characterize the intake levels of seafood, EPA, DHA, and other dietary constituents, and to assess the variability of those intakes.

7. Chicken and eggs, although not particularly rich sources, have contributed over 10 percent of the EPA and about 25 percent of the DHA in the US diet in recent years because of their frequent consumption. However, changes in feeding practices may be making these contributions negligible. New forthcoming data on chicken and eggs show most nutrient levels comparable to earlier samples, but EPA/DHA levels as undetectable.

8. Shrimp and tuna are the two most commonly consumed types of seafood in the United States. Shrimp and canned/packaged light tuna—the major type of tuna consumed—are not especially rich in EPA and DHA; nor are they especially high in mercury. However, albacore (white) tuna, a good source of EPA/DHA, can be higher in mercury than other tuna.

9. Shark, swordfish, king mackerel, and tilefish—the four types of seafood identified in the FDA/US EPA joint advisory as being most highly contaminated with mercury—are not among the types of seafood most frequently consumed in the United States, and supply trends suggest their future availability will be increasingly limited.

10. Forces such as consumer trends, increasing dependence on aquaculture, and increased imports are influencing the availability of many popular seafood selections.

RESEARCH RECOMMENDATIONS

Recommendation 1: Research is needed on systematic surveillance studies of targeted subpopulations. Such studies should be carried out using state-of-the-art assessment methods to determine the intake levels of seafood, EPA/DHA and other dietary constituents, and the variability of those intake levels among population groups.

Recommendation 2: Sufficiently large analytic samples of the most common seafood types need to be obtained and examined. These samples should be used to determine the levels of nutrients, toxicants, and contaminants in each species and the variability between them, which should be reported transparently.

Recommendation 3: Additional data is needed to assess benefits and risks associated with seafood consumption within the same population or population subgroup.

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3

Health Benefits Associated with Nutrients in Seafood

This chapter reviews the evidence for benefits derived from nutrients in seafood or from dietary supplementation with nutrients derived from seafood. The review of evidence related specifically to the omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) from seafood is presented in two parts: Part I addresses the impact of EPA/DHA on maternal, infant, and child health outcomes and Part II addresses the impact on chronic disease, particularly coronary heart disease, in adults. The discussions that follow include a review of the literature and evaluation of the quality of the evidence for benefits.

The committee considered a broad range of evidence on potential benefits associated with nutrients from seafood and reviewed evidence from other systematic reviews, i.e., the Agency for Health Research and Quality (AHRQ) reviews (Balk et al., 2004; Schachter et al., 2004, 2005; Wang et al., 2004) and other published reports of evidence associating nutrients from seafood with specific health outcomes. In cases where benefits were not supported or were poorly supported by the literature, a statement is made to that effect.

Scientific evidence to support benefits associated with seafood intake on cardiovascular risk reduction through prevention of disease development consists mainly of observational studies of seafood consumption among the general population. Recommendations to the general population are inferred from these findings despite the fact that they have not been tested by trials in this population. Fish-oil supplementation, on the other hand, has been used in secondary prevention trials in high cardiovascular-risk

populations or populations with established disease to examine its role in preventing recurrence of cardiovascular events.

Given the potential for different outcomes in general compared to high-risk populations, the committee also considered best practice guidelines for both, which take into account currently available evidence. The conclusions drawn from the evidence reviewed were the basis for decision-making about seafood selections discussed in later chapters. The literature reviewed in the chapter is summarized in tables included in Appendix B.

INTRODUCTION

Seafood is a food source comparable to other animal protein foods in nutrient composition (see Chapter 2). In addition, seafood is an important contributor of selenium to the American diet and is unique among animal protein foods as a rich source for the omega-3 fatty acids EPA and DHA, although the roles of these fatty acids in maintaining health and preventing certain chronic diseases have not been completely elucidated (IOM, 2002/2005).

Benefits to the General Population Associated with Nutrients in Seafood

As noted in Chapter 1, the US *Dietary Guidelines for Americans* (DGA) provides science-based advice to promote health and reduce risk for chronic diseases through diet and physical activity. The guidelines are targeted to the general public over 2 years of age living in the United States. But as noted in Chapter 2, general adherence to the DGA is low among the US population.

Seafood provides an array of nutrients that may have beneficial effects on health (see Chapter 2). While protein is an important macronutrient in the diet, most Americans already consume enough protein and do not need to increase their intake. Fats and oils are also part of a healthful diet, but the type of fat can be important, for example, with regard to heart disease. Many Americans consume greater than recommended amounts of saturated fat from high-fat animal protein foods such as beef and pork as well as trans fat from processed foods (Capps et al., 2002). A diet high in fat (greater than 35 percent of calories), particularly animal fat, may increase saturated fat intake, add excess calories, and increase risk for coronary heart disease. Many seafood selections, depending upon preparation method, are lower in total and saturated fat and cholesterol than some more frequently selected animal protein foods, including both lean and fatty cuts of beef, pork, and poultry (Table 3-1). By substituting seafood more often for other animal foods, consumers can decrease their overall intake of total and saturated fats while retaining the nutritional quality of other protein food choices.

TABLE 3-1 Differences in Saturated Fat Content Between Commonly Consumed Animal Food Products

Food Category	Portion Size (ounces)	Saturated Fat (grams)	Calories (kcal)
Cheese			
Regular cheddar cheese	1	6.0	114
Low-fat cheddar cheese	1	1.2	49
Ground beef			
Regular ground beef (25% fat)	3 (cooked)	6.1	236
Extra lean ground beef (5% fat)	3 (cooked)	2.5	145
Chicken			
Fried chicken (with skin)	3	3.4	229
Roasted chicken (no skin)	3	0.9	130
Fish			
Fried fish (catfish)	3	2.8	195
Baked fish (catfish)	3	1.5	129

SOURCE: USDA, Release 18.

The 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) identified several micronutrients that were consumed at levels below the Recommended Dietary Allowance (RDA), including vitamins E and B-6, calcium, iron, magnesium, and zinc. Seafood is a good source of zinc and some calcium, e.g., from canned salmon or other fish with bones, which may contribute to the total intake of these nutrients when substituted for other animal food products. For example, a 3-ounce cooked serving of beef, lamb, chicken, or pork contains approximately 10–20 mg of calcium, whereas a 3-ounce serving of canned salmon with bones contains approximately 240 mg. (Source: http://www.nal.usda.gov/fnic/foodcomp/Data/SR18/sr18.html.)

Nutritional Benefits Associated with Omega-3 Fatty Acids

Optimal Intake Levels for EPA and DHA

There are insufficient data on the distribution of requirements to set an Estimated Average Requirement (EAR) for alpha-linolenic acid (ALA), so an Adequate Intake (AI) was set instead, at approximately the level of current intakes (IOM, 2002/2005). Given that ALA conversion to EPA and DHA is low and variable (Burdge, 2004), intakes of the preformed omega-3 fatty acids may be less than desired under certain physiologic circumstances (see Chapter 2). Despite the number of studies conducted over the past two decades to assess the impact of omega-3 fatty acids in general on health outcomes, optimal intake levels for EPA and DHA are still not defined. The Dietary Reference Intakes (IOM, 2002/2005) did not establish a require -

ment for any omega-3 fatty acids; rather, an estimate of adequacy, the AI, was derived from the highest median intake of ALA in the United States.

Target intake goals for seafood consumption for the general population and recommended EPA/DHA intake levels for specific population subgroups have been put forward by both public agencies and private organizations (reviewed in Chapter 1). Whether there are benefits to the general population that are related specifically to EPA/DHA obtained from consuming seafood is not clear from the available evidence. A low-saturated-fat, nutrient-dense protein food such as seafood does represent a good food choice for the general population and this is reflected in the recommendations of the *Dietary Guidelines for Americans* to choose low-fat foods from among protein sources that include fish (see Chapter 1). The evidence in support of recommendations to increase EPA/DHA intake, whether from seafood or fish-oil supplements, among the population groups that would most benefit is presented in the following discussions.

It should, however, be kept in mind that the benefits of seafood consumption for health may not be limited to intake of EPA/DHA. Other nutrients present in seafood may provide specific health benefits or even facilitate the action of EPA/DHA. Additionally, substitution of seafood for other food sources may decrease exposure to nutrients that are shown to increase health risks, such as saturated fats. On the other hand, some contaminants or toxins present in seafood may decrease or negate the benefit of EPA/DHA, as illustrated by the dilemma in making recommendations for seafood consumption in pregnant women, considering the potential benefits of EPA/DHA compared to potential risks of methylmercury exposure to the fetus. Therefore, when assessing the question of benefits of seafood consumption, seafood should not be considered as equivalent to EPA/DHA. This differentiation may explain some of the inconsistencies in the findings described below. In other words, demonstrated benefits of EPA/DHA do not necessarily mean benefits of seafood, and lack of benefit from EPA/DHA does not necessarily mean lack of benefit from seafood.

Part I: Benefits to Women, Infants, and Young Children Associated with Omega-3 Fatty Acids

BENEFITS TO WOMEN DURING AND AFTER PREGNANCY

Preeclampsia

An array of studies based on supplemental intake of EPA/DHA or biochemical indicators of EPA/DHA levels has been carried out to determine whether there is an association between increased intake or blood levels of EPA/DHA and decreased incidence of or risk for preeclampsia (Olsen and Secher, 1990; Schiff et al., 1993; Williams et al., 1995; Velzing-Aarts et al., 1999; Clausen et al., 2001). Because these and other studies, including randomized clinical trials (Bultra-Ramakers et al., 1995; Onwude et al., 1995; Salvig et al., 1996) or reviews of trials (Sibai, 1998) did not show clear evidence of a beneficial effect of a broad range of intake (or biochemical indicators) of EPA/DHA levels, it does not appear likely that increased seafood intake or fish-oil supplementation will reduce the incidence of preeclampsia among US women (see Appendix Table B-1a).

Postpartum Depression

During pregnancy and lactation there is a correspondent transfer of DHA from the mother to the fetus or infant (Holman et al., 1991; Al et al., 1995). Following pregnancy and lactation, maternal DHA blood levels may require many months for recovery to pre-pregnancy levels (Otto et al., 2001). Although prior depressive illness is the best predictor of higher risk for postpartum depression, it has been proposed that low DHA levels in the brain in late pregnancy and early postpartum period may contribute to the emergence of postpartum depression (Hibbeln and Salem, 1995). Further, it has been hypothesized that increased EPA/DHA intake during pregnancy could reduce the risk for postpartum depression. To date, however, there have been no randomized controlled trials or controlled clinical studies testing whether increased omega-3 fatty acid intake by pregnant women could reduce the risk for postpartum depression.

Hibbeln (2002) conducted a cross-cultural review of 41 studies and concluded that there is an association between increased seafood consumption and higher maternal milk DHA levels ($p<0.006$) and that this was associated with a lower prevalence of postpartum depression ($p<0.0001$). Timonen et

al. (2004) followed up the Northern Finland 1966 Birth Cohort prospectively from pregnancy to 31 years of age. Members of the cohort were sent questionnaires, invited to undergo a clinical examination to assess indices of depression, and asked to estimate seafood consumption in the previous six months (presumably related to the lifetime pattern of seafood consumption). The study found that females who rarely consumed fish showed greater incidences of life-time depression than regular consumers of fish, based on the Hopkins Symptom Check List (HSCL-25) depression subscale alone (cutoff-point 2.01) (OR=1.4; 95% confidence interval [CI] 1.1-1.9) and the HSCL-25 depression subscale (cutoff-point 2.01) with a doctor diagnosis (OR=2.6; 95% CI 1.4-5.1), but not based on doctor diagnosis alone (OR=1.3; 95% CI 0.9-1.9) or suicidal ideation. This study, however, did not show causation and did not address postpartum depression specifically.

Otto et al. (2003) investigated the relationship between postpartum depression and changes in maternal plasma phospholipid-associated fatty acid (DHA and docosapentaenoic acid [DPA]) status by measurement at 36 weeks of pregnancy, at delivery, and 32 weeks postpartum in women in the Netherlands. Postpartum depression was assessed using the Edinburgh Postnatal Depression Scale (EPDS), developed as a screening and monitoring tool for postpartum depression (Cox et al., 1987). Only relative plasma fatty acid levels (percent of total fatty acids, wt/wt) were reported because total absolute amounts of plasma phospholipid-associated fatty acids at delivery and changes that occurred postpartum were not significantly different between the "possibly depressed" and "non-depressed" groups. The conclusion from this study was that the ratio of 22:6 n-3 (DHA) to 22:5 n-6 (DPA) becomes reduced during pregnancy and the difference is significant ($p<0.04$) compared to increased EPDS scores, while DHA status at delivery did not correlate with depressive symptoms ($p=0.563$) (Otto et al., 2003).

In contrast to the above-mentioned studies, Llorente et al. (2003) examined a cohort of 44 women who consumed 200 mg of DHA per day during the first 4 months of lactation compared to a placebo control group (n=45) for indices of postpartum depression and information processing (cognition). Both groups were analyzed for symptoms of depression using a self-rating questionnaire, the Beck Depression Inventory (BDI). Additionally, a subgroup of the population was administered the EPDS and the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Axis I Disorders—Clinical Version. A positive and statistically significant correlation was found between the BDI questionnaire at 4 months and the EPDS scores at 18 months ($p <0.0001$), which validated use of the BDI for assessment of symptoms. However, no difference was found between the supplemented and control groups for diagnostic measures of postpartum depression or information processing (see Appendix Table B-1b).

Summary of Evidence

Based solely on these studies, the committee cannot draw a conclusion about the effect of increased EPA/DHA on postpartum depression. Thus, there is not sufficient evidence to conclude that the health of pregnant or lactating women will benefit directly from an increase in seafood intake.

BENEFITS TO INFANTS AND CHILDREN ASSOCIATED WITH PRENATAL OMEGA-3 FATTY ACID INTAKE

Transfer of Maternal DHA to the Fetus or Breastfeeding Infant

The level of maternal DHA intake influences DHA levels in both maternal blood and milk. Blood DHA levels increase by about 50 percent in pregnancy (Al et al., 1995) and decline dramatically by 6 weeks after parturition, especially with lactation (Makrides and Gibson, 2000; Otto et al., 2001). DHA transport across the placenta is increased with higher compared to lower maternal blood DHA concentration and, compared with other fatty acids in maternal blood, DHA is selectively transferred across the placenta (Haggerty et al., 1997, 1999, 2002). Thus, increased maternal blood DHA levels in pregnancy may enhance DHA availability for placental transfer to the fetus.

Maternal DHA status could influence the DHA supply available to the fetal brain as well as other organs and tissues (Clandinin et al., 1980a). Brain DHA accumulates rapidly from approximately 22 weeks gestation until at least 2 years after birth (Clandinin et al., 1980b; Martinez, 1992). Studies that examined autopsy tissue from a limited number (n = 5) of both preterm and term infants reported that tissue from infants who consumed breast milk after birth showed greater cortical accumulation of DHA than those fed formulas that did not contain DHA, and the differences increased with duration of feeding (Farquharson et al., 1992; Makrides et al., 1994).

Duration of Gestation and Birth Weight

Infant birth weight is the result of a complex interaction involving many factors, including both biological and social mechanisms. Biological mechanisms are also variable and complex but appear to be linked to duration of gestation and fetal growth, conditional on duration of gestation (Ghosh and Daga, 1967; Villar and Belizan, 1982; Alberman et al., 1992). Higher birth weight is positively associated with cognitive ability among full-term infants in the normal birth weight range (Matte et al., 2001; Richards et al., 2001) as well as some preterm infants (Hediger et al., 2002). Low infant birth weight (less than 2500 grams or 5.2 pounds) (Juneja and Ramji, 2005), fetal

growth retardation (van Wassenaer, 2005), and preterm delivery (Hediger et al., 2002) are associated with poor developmental outcomes.

Fish-Oil Supplementation

Observational and experimental studies have been carried out to determine if there is a relationship between DHA intake and increased gestation duration or birth weight. Both observational and experimental studies suggest that increased seafood consumption or DHA intake from supplements can increase gestation duration or birth weight. Any outcome correlated with a variable in an observational study can only suggest an association. In the case of the observational studies cited here showing relationships between EPA/DHA or seafood intake, the effect may be explained by these variables or by other variables that accompany diets higher in EPA/DHA or seafood intake. The People's League of Health trial (reviewed in Olsen, 2006) showed that deliveries before 40 weeks were reduced by 20.4 percent in the group that received a fish-oil/vitamin supplement compared to the group that was not supplemented ($p<0.0008$) (Olsen and Secher, 1990).

Several randomized controlled trials (RCT) have tested for an association between dietary supplementation with fish oil or the omega-3 fatty acids from fish oil (i.e., either DHA alone or EPA and DHA) and longer duration gestation. Olsen et al. (1992) conducted an RCT that administered 2.7 g/day of a fish-oil supplement beginning in the 30th week of pregnancy in a Danish cohort. The study found an average increase in gestation of 2.8 days in subjects from the fish-oil treatment group compared with control groups receiving an olive oil supplement or no supplement ($p <0.01$). In a similar study, Olsen et al. (2000) found among women who had a previous preterm delivery (delivery at <37 weeks) a significantly decreased risk for recurrent preterm delivery, a mean increase in gestation of 8.5 days ($p=0.01$), and an increase in birth weight of 209 g ($p=0.02$) in the fish oil compared to the olive-oil treatment group. In this study, however, prophylactic trials using fish-oil supplementation did not increase gestation duration and birth weight in pregnancies with intrauterine growth retardation, twins, or pregnancy-induced hypertension.

In contrast to these studies, a randomized trial conducted in Norwegian women (Helland et al., 2001) found no increase in either gestation duration or birth weight with a supplement of 2 g/day of EPA and DHA from cod-liver oil during the last two trimesters of pregnancy. However, a post hoc analysis found an increase in length of gestation of 7 days in infants in the highest quartile for plasma phospholipid DHA compared to those in the lowest quartile (Helland et al., 2001). Similarly, a post hoc analysis of results from the previously mentioned Danish trial (Olsen et al., 1992) found an increase in gestation duration of 5.7 days associated with fish-oil supple

mentation in a group of women who had the lowest 20 percent of seafood consumption at study entry ($p < 0.05$), compared to a 2.8-day increase in gestation associated with fish-oil supplementation in all women.

The committee found that compared to women in Denmark and Norway, US women have been shown to consume less omega-3 long-chain polyunsaturated fatty acids and have lower levels of DHA in breast milk (Jensen et al., 1995). They also have, on average, shorter gestation durations and smaller infants (Smuts et al., 2003 a,b; Olsen et al., 1992; Helland et al., 2001). Birth weight depends on both length of gestation and intrauterine growth. Problematically high birth weight is not due to excessive gestation but rather to excessive intrauterine growth. No experimental trials have been conducted in the United States in which fish-oil supplements were evaluated for increasing gestation duration.

EPA/DHA Intake from Seafood and Other Food Sources

In a randomized controlled trial, Smuts et al. (2003b) evaluated the effect of feeding DHA-fortified eggs (mean 133 mg DHA/egg) to pregnant women in the United States, beginning at 24–28 weeks gestation. They reported a significant increase in gestation of 6 days among women consuming the high-DHA eggs compared to women receiving unfortified eggs (mean 33 mg DHA/egg). There was no significant increase in birth weight ($p=0.184$), birth length ($p=0.061$), or head circumference ($p=0.081$) among infants of mothers consuming high-DHA eggs. Although birth weight is frequently used as a marker for infant growth, head circumference and birth length are likely better indicators of positive pregnancy outcome.

An observational study examining an association between seafood consumption and gestational duration was conducted in a cohort of women in the Orkney Islands and Aberdeen, Scotland. This study identified a significant association between the 30 percent greater amount of seafood consumed by Orkney Island women over that consumed by women in Aberdeen, Scotland, and an increase in gestational duration of 2.5 days ($p=0.01$) (Harper et al., 1991).

Olsen et al. (1991) examined whether there was a difference in the ratio of the long-chain polyunsaturated fatty acids (LCPUFA) EPA, DPA, and DHA to arachidonic acid (AA) measured in erythrocytes obtained within 2 days of delivery between Faroese and mainland Danish women and whether there was a correlation between the LCPUFA levels and gestational duration in these populations. Among the Faroese subjects, significantly higher percentages of blood EPA and DHA were detected compared to Danish subjects, whereas DPA and AA values in both groups were similar. The Faroese subjects were found to have a gestational duration an average of 2 days longer ($p=0.3$) and a corresponding higher birth weight of 140 g

(p=0.1) compared to the Danish subjects, but these differences were not significant. After making allowance for seven potential confounders, an increase in duration of gestation of 5.7 days was found for each 20 percent increase in the ratio of erythrocyte EPA and DHA to AA in the Danish women (95% CI 1.4-10.1 days; p=0.02), but not in Faroese women (95% CI –2.0 to 3.3; p=0.6).

Increased gestational duration has also been investigated using observational studies of women who consumed seafood in geographical locations where there was higher exposure to environmental contaminants. Grandjean et al. (2001) examined a birth cohort from the Faroe Islands whose mothers consumed the meat and blubber from pilot whales in addition to regional fish. In a questionnaire, the women reported that they consumed, on average, 72 g of fish, 12 g of whale meat, and 7 g of whale blubber per day (Grandjean et al., 2001). The estimated intake of polychlorinated biphenyls (PCBs) for these women was 30 ∝g/g of blubber, and of mercury was 2 ∝g/g of whale meat (Grandjean et al., 2001). In addition to the increase in contaminant concentrations, there was an approximate 10-fold molar excess of selenium over mercury in serum samples from the subjects. The concentration of EPA in the cord [1] serum from the infants of Faroese subjects was strongly associated with a maternal diet rich inmarine fats. Gestational length showed a strong positive association with cord serum DHA concentration. Each 1 percent increase in the relative DHA concentration in cord serum phospholipids was associated with an increased duration of 1.5 days (95% CI 0.70-2.22), supporting the hypothesis that increased seafood intake may prolong gestation.

Lucas et al. (2004) concluded from an observational study that infants of the Inuit in Nunavik, Canada, had 2.2-fold higher omega-3 fatty acid ($p<0.0001$), 18.6-fold higher mercury ($p<0.0001$), 2.4-fold higher lead (presumably related to maternal smoking as ~85 percent of pregnant Inuit women studied smoked) ($p<0.0001$), and 3.6-fold higher PCB congener 153 cord blood levels ($p<0.0001$) compared to levels from infants in southern Québec. Despite the association of seafood intake with environmental contaminants, however, the Nunavik women whose infants were in the third compared to the first tertile of percentage of omega-3 fatty acid out of total highly unsaturated fatty acid (HUFA) cord blood values still had a mean 5.4-day longer gestation duration (95% CI 0.7-10.1; $p<0.05$). This study also showed a nonsignificant increase in mean adjusted birth weight in the third, compared to the first, tertile among Inuit (difference = 77 g, 95% CI –64 to 217).

[1]Examining the blood remaining in the umbilical cord after birth, though it is not precisely identical to that in the infant bloodstream, provides a noninvasive way to approximate the infant's blood profile.

Infants born preterm are at higher risk for neonatal complications and developmental delay. A reduction in the incidence of preterm birth (birth at <37 weeks) is desirable and could be associated with an increase in gestation duration among this at-risk population. Olsen and Secher (2002) evaluated the risk of preterm birth in relation to seafood intake in a prospective cohort study in Denmark. A questionnaire was used to evaluate intake of seafood, including roe, prawn, crab, and mussels, as well as fish-oil supplements, among participants. Quantification of fish consumption and EPA/DHA intakes was based on assumptions about the type and amount of fish reported in the questionnaire. Results of the analysis were based on seafood consumption only, since very few of the subjects took fish-oil supplements. Among the respondents, there was a trend of decreasing incidence of low birth weight, preterm birth, and intrauterine growth retardation with increasing fish consumption and increasing mean birth weight and duration of gestation among subjects. Women who were not smokers, primiparous women, teenagers, and women who had low weight, short stature, and without a high school education and cohabitant tended to fall into the low exposure group. This group had 3.57 (95% CI 1.14-11.14) times the risk of preterm birth and 3.60 (95% CI 1.15-11.20) times the risk of low birth weight (< 2500 g) delivery compared to women who consumed the highest amount of seafood. This study could be interpreted to suggest that a relatively low threshold intake of seafood EPA and DHA may increase gestation duration. However, Oken et al. (2004) found no relationship between seafood EPA and DHA intake and duration of gestation or risk of preterm birth in US women from Massachusetts.

Summary of Evidence

In summary, observational studies suggest and several experimental studies support that EPA/DHA supplementation or higher seafood intake is associated with an increased duration of gestation. In trials that show longer gestation duration, the populations studied varied markedly in both baseline EPA and DHA blood levels and in estimated amounts of EPA and DHA provided from supplements (see Appendix Table B-1c). The clinical significance of increased duration of gestation is not clear. In general, health professionals consider that the fetus benefits from a longer time in utero up to the point that the fetus is >4500 g, although the advantage remains theoretical.

Development in Infants and Children

During pregnancy, AA and DHA are delivered to the fetus via the placenta (Crawford et al., 1997). Hornstra et al. (1995) found that maternal essential fatty acid status progressively declines during pregnancy. There ap-

pears to be a greater transplacental gradient in proportions of AA and DHA at term than midterm. Such a difference is consistent with the decline in plasma concentration of DHA between the beginning and end of pregnancy and suggests that the placenta is progressively depleting maternal DHA as the fetus grows (Crawford, 2000). Although the mechanism of transport for AA and DHA has not been elucidated, Campbell et al. (1998) proposed and Larque et al. (2003) identified a fatty acid binding protein, p-FABPpm, in placental tissue that showed a higher binding capacity for DHA and AA than linoleic acid (LA) and oleic acid (OA).

Visual Acuity and Sensory-Motor Development

Because lower visual acuity was observed in rhesus monkeys with lower brain DHA ($p < 0.001$) (Neuringer et al., 1984), this outcome has been the most studied in human infants relative to DHA intake. The first experimental studies that provided DHA, AA, and EPA to preterm infants demonstrated an increase in blood lipid content of these fatty acids as well as increases in visual acuity (Uauy et al., 1990; Carlson et al., 1993). Subsequently, DHA in cord blood and infant blood lipids has been used as an indicator of DHA exposure of the fetus or infant.

DHA status in infants is determined using blood as a biomarker because levels of DHA in the brain correlate with those in erythrocytes (Makrides et al., 1994). Previous studies have identified a correlation between dietary intake of AA, DHA, and other LCPUFAs; their respective levels in blood and erythrocyte phospholipids; and performance on tests of visual acuity and sensory-motor development in preterm infants (Uauy et al., 1990; Bjerve et al., 1993; Carlson et al., 1993). Observational studies that associate higher maternal EPA or DHA intake with higher stereoacuity or visual acuity in their infants are discussed below. Subsequently, maternal EPA/DHA supplementation or biochemical markers for their intake have been assessed as indicators of an association between increased intake levels of EPA/DHA and improved sensory-motor development in infants and young children.

Williams et al. (2001) observed that stereoacuity at 3.5 years of age in a subset of 435 healthy full-term children from the Avon Longitudinal Study of Parents and Children (ALSPAC) cohort was associated with breast feeding, greater maternal age, and maternal antenatal consumption of fatty fish. After multiple logistic regression, only breastfeeding and maternal consumption of fatty fish at least once every 2 weeks remained significant predictors of higher stereoacuity (foveal acuity) in the children. Among 4733 women in the main ALSPAC cohort for whom both dietary intake and red blood cell DHA percentage were available, only intake of fatty fish was associated with higher red blood cell DHA levels, an indicator of higher maternal DHA status. Higher maternal DHA intake is also known to

increase human milk DHA (Jensen et al., 2005). Therefore, both variables associated with significantly higher stereoacuity are themselves influenced by maternal DHA intake, and both could be expected to result in increased DHA exposure of the fetus or infant.

Innis et al. (2001) conducted a prospective observational study of 83 infants who were breastfed at least 3 months. Blood and plasma fatty acid status were determined at 2 months; visual acuity at 2, 4, 6, and 12 months; and speech perception and object search at 9 months. Maternal milk DHA content was measured as an indicator of maternal DHA status, and this was linked with higher visual acuity ($p<0.01$) and higher ability to discriminate nonnative retroflex and phonetic contrasts ($p<0.02$) in infants at 2 months of age (see Appendix Table B-1d). Both of these tasks suggest more mature sensory development; however, additional measures would be required to make a definitive determination. Placement in front of the Teller Acuity Cards (the technique employed to measure visual acuity) does not require motor development such as head turning, but it is required on the infants' performance on head-turning in response to sound. Thus, associations of DHA with motor function cannot be ruled out, particularly for the task related to hearing. Differences in cognitive development (discussed in the next section) also cannot be ruled out as a possible explanation for the association. However, factors that have been associated with cognitive development in infancy include speed, attention, and memory (Jacobson et al., 1992; Rose et al., 2004).

Cognitive Development

Cognitive developmental outcome has been assessed in a single randomized controlled trial in children born to women supplemented with EPA and DHA during pregnancy (see Appendix Table B-1d). Helland et al. (2001, 2003) evaluated children whose mothers consumed 2 g/day of DHA and EPA from cod liver oil for the last two trimesters of pregnancy compared with children of those receiving a corn oil supplement as control and found significantly higher Mental Processing Composite scores at 4 years of age in the children of supplemented mothers ($p=0.049$). Women continued to consume the cod-liver oil supplements or the control oil during lactation, most of the infants were breastfed, and infants from both groups began to receive a fish-oil supplement at ~1 month of age. The analysis of results suggested that all of the increase in IQ at 4 years of age was attributed to prenatal rather than postnatal exposure to EPA and DHA. The trial was conducted in Norwegian woman, whose seafood consumption considerably exceeds that of US women.

Auestad et al. (2001) found that breast milk DHA levels between Norwegian women in the control group was 0.51 percent compared to DHA

levels of 0.12 percent reported in breast milk of US women. Although the results of this study suggest that provision of EPA and DHA to neonates through supplemented formula might be greater than can be easily achieved through the diet, other investigators have reported higher levels of DHA in human milk than those reported by Auestad et al. (2001). Birch et al. (1998) compared visual acuity among infants who were fed DHA- and/or AA-supplemented formula with infants fed unsupplemented formula and breastfed infants. In comparing the red blood cell content of DHA among the infant groups, there was no significant difference in DHA level between the DHA-supplemented group and the breastfed group at week 0 and at week 52. However, there was a significant difference at week 17. In addition, a significant difference in the red blood cell AA concentration was found between the DHA-supplemented and breastfed groups only at week 17. As with the findings of Auestad et al. (2001), Birch et al. found that dietary supply of DHA is associated with optimal visual acuity.

Jensen and co-workers (2005) hypothesized that DHA supplementation of breastfeeding women would increase the DHA content of plasma lipids and improve visual and neuropsychological development in their infants. Women who planned to breastfeed were randomly assigned in a double-blinded manner to receive either a 200-mg algal DHA supplement or a control mixture of 50:50 soy and corn oil for the first 4 postnatal months. The results showed an increase in milk lipid and plasma phospholipid DHA levels of 75 and 35 percent, respectively, in the DHA-supplemented compared to control groups at 4 months. No differences were seen between supplemented and unsupplemented groups in either developmental indexes at 12 months or in visual acuity at 4 or 8 months. DHA-supplemented children subsequently showed higher Bayley Psychomotor Development scores at 30 months of age ($p=0.005$); and, in an earlier report, longer sustained attention at 5 years of age (Jensen et al., 2005). These outcomes suggest that 4 months of postnatal DHA supplementation via mother's milk is associated with long-term motor and cognitive development as defined by the Bayley Psychomotor Development score in US children. Because neither the experimental trial by Helland et al. (2003) nor that by Jensen et al. (2005) found benefits in infancy from maternal DHA supplementation, but both found benefits in early childhood, these trials suggest that studies that stopped developmental follow-up in infancy may have missed benefits to children of improving maternal omega-3 fatty acid intake. These findings also suggest that the benefit of perinatal DHA intake may only be manifested after a latency period.

Oken et al. (2005) in a prospective observational cohort study of pregnant women from Massachusetts, Project VIVA (see Box 3-1), examined associations of maternal fish intake during pregnancy and maternal hair mercury at delivery with infant cognition in a subset for which these data

BOX 3-1
Longitudinal Studies of Beneficial Outcomes to Women and Children from Seafood Consumption

Project Viva

Project Viva is a longitudinal study of women and their children, investigating the "effects of mother's diet and other factors during pregnancy on her health and the health of her child."

From 1999 to 2002, more than 2600 pregnant women were enrolled from eight different Harvard Vanguard Medical Associate sites in the greater Boston area. Participating expectant mothers completed standardized interviews (on diet, exercise, medical history, stress, societal factors, and financial support) and provided blood samples several times during and after their pregnancies.

Participating mothers were also asked to enroll their babies in the study. Research assistants interviewed the mothers and measured the newborns' body size and blood pressure in the first few days after birth (1703 women and 1203 newborns) and 6 months later (1266 mothers and 1210 babies). Hair samples from 210 women and umbilical cord blood from 1022 participants were also collected at delivery, and developmental tests were performed on the infants at 6 months of age.

At the child's first, second, and fourth birthdays, the mothers were sent a questionnaire asking about their child's health, diet, and environment, and at their third birthday, research assistants measured body size and blood pressure and performed additional developmental tests. The mother and child were also asked for another blood sample.

The Project Viva investigators hope to follow the Viva children throughout their lives, and are currently pursuing additional funding opportunities. The information provided here, along with updates, articles, facts, etc., can be accessed at http://www.dacp.org/viva/index.html [accessed November 2, 2005].

Avon Longitudinal Study of Parents and Children (ALSPAC)

"The Avon Longitudinal Study of Parents and Children (ALSPAC) also known as 'Children of the 90s' is aimed at identifying ways in which to optimize the health and development of children. The main goal is to understand the ways in which the physical and social environments interact, over time, with the genetic inheritance to affect the child's health, behavior and development."

Over 14,500 pregnant women, resident in Avon, UK, were enrolled in this study, along with almost 14,000 of their children. Throughout their pregnancies, expectant mothers (and sometimes their partners) received various questionnaires to identify features of the early environment that might affect the fetus and to acquire information on the mother's

continued

BOX 3-1
Continued

demographic characteristics; past medical, social, and environmental history; and attitudes, activities, and emotional well-being. Maternal blood and urine samples were also obtained when the mothers gave routine samples at their respective clinics.

During delivery, cord blood and umbilical cord samples were collected, along with the placentas from births at two major hospitals. After delivery, further questionnaires were distributed to both the mothers from 4 weeks and throughout the next 9.5 years and to the children from 65 months until 9.5 years of age. During these years, samples of the child's hair and nail clippings, primary teeth, blood, and urine were also collected. For a complete list of topics covered on all questionnaires, see the ALSPAC website (http://www.ich.bristol.ac.uk/protocol/section3.htm).

"ALSPAC has the long-term aim of following the children into adulthood and thus will be set to answer questions related to prenatal and postnatal factors associated, for example, with schizophrenia, delinquency, and reproductive failure on the one hand, and realisation of full educational potential, health and happiness on the other." The information provided here, along with updates, articles, facts, etc., can be accessed at http://www.ich.bristol.ac.uk/welcome/index.shtml [accessed May 30, 2006].

were available. After adjusting for participant characteristics with linear regression, higher cognitive performance was associated with higher seafood intake. Each additional serving of fish per week was associated with a 4-point higher visual recognition memory (VRM) score at 6 months of age (95% CI 1.3-6.7), although an increase of 1 ppm in mercury was associated with a decrement in the VRM score of 7.5 (95% CI –13.7 to –1.2). VRM scores were highest among infants of women who consumed more than 2 servings of fish per week and had hair mercury levels less than or equal to 1.2 ppm. The study concluded that higher fish consumption was associated with better infant cognition but higher mercury levels were associated with lower cognition.

Daniels et al. (2004) studied a subset of 1054 children from the British ALSPAC cohort (see Box 3-1) for associations between maternal fish intake during pregnancy and infant development of language and communication skills in relation to mercury exposure. This study found an association between maternal fish intake during pregnancy and comprehension on the MacArthur Communicative Development Inventory (MCDI) (consumption of 1–3 or 4+ fish meals/week decreased odds of a low MCDI score, $p<0.05$) and the Denver Developmental Screening Test (DDST) (consumption of 1–3

or 4+ fish meals/week decreased odds of a low DDST score, $p < 0.05$) at 15 and 18 months, respectively. In this cohort, mercury levels were low and not associated with measures of neurodevelopment. Similar findings of association between maternal DHA status and more mature attentional development in infancy (Willatts et al., 2003b; Colombo et al., 2004) and lower distractibility among toddlers (Colombo et al., 2004) were reported.

Some animal studies suggest that low brain DHA early in development produces adverse effects on behavior that are not reversible even when brain DHA content is returned to normal (Kodas et al., 2004; Levant et al., 2004). No studies have been designed to address possible programming of development in human infants, but the animal work suggests that timing of brain DHA accumulation should be considered as a variable in human studies.

Sleep Patterns

Cheruku et al. (2002) investigated whether central nervous system integrity in newborns, measured with sleep recordings, was associated with maternal DHA status. Plasma phospholipid fatty acids, including DHA, were measured in 17 women at parturition, and infant body movement and respiratory patterns were measured on postpartum days 1 and 2. Infants born to mothers in the high-DHA group had significantly lower ratios of active compared to quiet sleep patterns and less total active sleep compared to infants of low-DHA mothers. The conclusion from this study is that infants born to mothers with higher plasma DHA had more mature sleep patterns ($p < 0.05$) compared to infants of mothers with lower plasma DHA levels (see Appendix Table B-1d).

Infant and Child Allergy

Few studies have been carried out to examine whether supplementation with fish oil is associated with reducing the inflammatory responses to allergens. Hodge et al. (1998) assessed the clinical and biochemical effects in asthmatic children of fish-oil supplementation and a diet that increases omega-3 and reduces omega-6 fatty acids. Although the supplemented group had higher plasma levels of omega-3 fatty acids and lower stimulated tumor necrosis factor-± production, there was no effect of the intervention on the clinical severity of asthma in the children. Dunstan et al. (2003) examined associations between fish-oil supplementation and levels of immune factors (cytokines and IgE) in a randomized, double-blind, placebo-controlled trial. No significant differences were found in interleukin (IL-13) ($p = 0.025$) and cytokine levels within the treatment group, except that neonates of supplemented mothers had significantly lower levels of IL-13. In a subset of children from the ALSPAC cohort, Newson et al. (2004) found no relationship

between cord and maternal red blood cell EPA/DHA and either eczema at 18 to 30 months ($p>0.05$) or wheezing at 30 to 42 months ($p>0.05$). These findings do not provide strong support for the hypothesis that exposure to omega-3 fatty acids from fish oil in utero or through breast milk could decrease the incidence of wheezing and atopic disease in early childhood (see Appendix Table B-1e).

Summary of Evidence

The strongest evidence of benefit for higher maternal seafood or EPA/DHA intake is an increase in gestation duration, with anticipated benefits to the newborn. Populations or subgroups within populations who have the lowest baseline consumption of seafood may show the greatest benefit in duration of gestation with higher EPA/DHA intake. Observational and experimental studies offer evidence that maternal DHA intake can benefit development of the offspring; however, there are large gaps in knowledge that need to be filled by experimental studies.

The average EPA/DHA intake among US women is considerably below that of most other populations in the world and the majority of the data on benefits to infants and children from increased DHA levels comes from populations outside the United States and/or from studies using supplementation rather than seafood consumption.

BENEFITS TO INFANTS FROM POSTNATAL SUPPLEMENTATION THROUGH FORMULA

Although the focus of this report is seafood intake, the committee reviewed evidence for benefits associated with DHA-supplemented infant formulas to consider whether this data supports the previously discussed findings on benefits associated with seafood consumption or fish-oil supplementation in pregnant and lactating women. Formula-fed infants have much lower red blood cell phospholipid DHA levels than breastfed infants (Putnam et al., 1982; Carlson et al., 1986; Sanders and Naismith, 1979). DHA supplementation may increase brain DHA levels and improve visual acuity and various behavioral domains that are dependent upon brain function. Since 2002, infant formulas supplemented with DHA from algal oil in combination with a fungal source of AA have been commercially available in the United States. Randomized clinical trials have been conducted using a variety of sources of EPA/DHA including fish oil, tuna eye socket oil, egg phospholipid, total egg lipids, and algal oils to test for associations between DHA supplementation and improved developmental outcomes in formula-fed infants.

Visual Acuity

Studies by Carlson et al. (1993; 1996a,b; 1999) have tested the effect of DHA-supplemented formula on infant visual acuity using the Teller Acuity Card (TAC) procedure. The TAC procedure is subjective because it assesses an integrated behavioral response and may be influenced by nonvisual factors such as alertness, attention, and motor control (Lauritzen et al., 2001). Studies using the TAC procedure found significantly higher visual acuity in the groups receiving supplemented formula; higher visual acuity was found throughout infancy in trials that employed the sweep visual evoked potential (VEP) acuity procedure (Birch et al., 1992, $p < 0.025$; 1998, $p < 0.05$). VEP measures involve placing electrodes over the visual cortex to measure responses to different grating stimuli. This is not a subjective measure of visual acuity and also is more sensitive at detecting the threshold of visual acuity.

Higher VEP acuity was also found in studies on term infants that used formulas supplemented with both DHA and AA after weaning from breast milk (Hoffman et al., 2003, $p < 0.0005$; Birch et al., 2002, $p < 0.003$). Two trials that measured VEP acuity in preterm (Bougle et al., 1999) and term infants (Makrides et al., 2000) did not find any association between infant visual acuity and DHA-supplemented formula. However, these studies measured acuity using a flash of light rather than a sweep of high-contrast bands of graded spatial frequencies.

With the exception of Bougle et al. (1999), all of the previously discussed preterm infant trials and about half of the term infant trials that measured visual acuity have found higher visual acuity at some age. Uauy et al. (2001) in a review and San Giovanni et al. (2000a,b) in meta-analyses of previous studies concluded that DHA supplementation of infant formula was beneficial to visual acuity development in both preterm and term infants. A Cochrane systematic review of nine randomized controlled trials, however, concluded that there was no association between DHA supplementation and increased visual acuity or general development in term infants (Simmer, 2005) (see Appendix B-1f).

Cognitive and Motor Development

Many of the experimental trials that have studied postnatal DHA supplementation have also measured nonvisual developmental outcomes, most commonly global scales of development such as the Bayley Scales of Infant Mental Development Index (MDI) and Psychomotor Developmental Index (PDI) or a related test, Brunet-Lezine's developmental quotient (see Appendix Table B-1g). The majority of the extant published trials were reviewed by Gibson et al. (2001) and Uauy et al. (2001). Two trials in term infants found

higher apparent motor development in infancy with DHA supplementation, as tested by the motor aspect of the Brunet-Lezine ($p<0.05$) (Agostoni et al., 1995) or general movement assessment ($p=0.032$) (Bouwstra et al., 2003). However, neither study found any benefit for movement or psychomotor development when the infants were tested again at 18 months of age. Birch et al. (2000) found higher (by 7 points) Bayley MDI scores at 18 months of age in term infants who consumed a formula supplemented with DHA and AA, compared to those who consumed the control formula ($p <0.05$), whereas Lucas et al. (1999) found no benefit of DHA and AA on either the Bayley MDI or PDI of term infants at 18 months of age.

It has been hypothesized that preterm infants may benefit more than term infants from DHA supplementation. Fewtrell et al. (2002, 2004) found no effect of supplementation on Bayley MDI of preterm infants in two other larger longitudinal studies.

Among smaller studies in preterm infants, however, Clandinin et al. (2005) in a randomized controlled trial found significant increases in both the Bayley MDI and PDI in preterm infants given DHA- and AA-supplemented formula ($p <0.05$) whereas van Wezel-Meijler et al. (2002) did not; Carlson et al. found higher Bayley MDI but not PDI at 12 months in only one of two preterm trial (Carlson et al., 1994, 1997).

Global tests such as the Bayley Scales of Infant Development and the Brunet-Lezine administered in infancy may be less related to performance on cognitive tests in childhood than more specific tests of attention and problem-solving (Carlson and Neuringer, 1999; Jacobson, 1999). While there is limited evidence from global tests of infant development (e.g., higher Bayley MDI scores in properly powered trials) to conclude there may be cog nitive benefits of DHA supplementation for either preterm or term infants, evidence in support of benefits associated with DHA supplementation from specific tests in infancy that are more strongly related to several develop - mental parameters is mixed. O'Connor et al. (2001) assessed, among other measures, developmental outcomes in infants who received DHA- and AA-supplemented formula compared to controls. No differences were found in the Bayley MDI at 12 months, although the motor development index scores were higher among the supplemented infants who weighed less than 1250 g at birth compared to the nonsupplemented controls ($p=0.007$). When Spanish-speaking and twin infants were excluded from the analyses scores for the MacArthur Communicative Development Inventories, the supple - mented infants had higher vocabulary comprehension at 14 months ($p=0.01$ for the egg triglyceride/fish group; $p=0.04$ for the fish/fungal group).

While there is limited evidence from global tests of infant development (e.g., higher Bayley MDI scores in properly powered trials) to conclude there may be cognitive benefits of DHA supplementation for either pre - term or term infants, there is collective evidence of benefits associated with

supplementation from specific tests in infancy that are better related to later cognitive function, e.g., higher novelty preference (O'Connor et al., 2001, p=0.02); duration of looking (Carlson and Werkman, 1996, p<0.05; Werkman and Carlson, 1996, p <0.05); and problem-solving (Willatts et al., 1998a, p=0.021; 1998b, p <0.02); although, excepting Willatts et al., these benefits have been found in preterm infants. Infants who received the supplemented formula had significantly more intentional solutions than infants who received the control formula (median 2 vs. 0; p=0.021). Intention scores (median 14.0 vs. 11.5; p=0.035) were also increased in this group (Willatts et al., 1998a).

Among studies assessing postnatal DHA supplementation, Willatts et al. (2003a) identified a long-term cognitive benefit, specifically, higher scores and speed on the matching familiar figures test (MFFT) at school age, in children provided DHA formula supplementation compared to unsupplemented formula as infants. Cognitive benefits reported at school age after postnatal supplementation are longer sustained attention at 5 years (Jensen et al., 2004) and higher IQ at 4 years of age noted in children exposed to higher DHA through maternal supplementation (Helland et al., 2003).

Language is highly associated with IQ, and studies that have assessed some aspect of early language are included here under the general topic of cognitive function. Scott et al. (1998) reported lower vocabulary comprehension (p=0.17) and production scores (p=0.027) with the MacArthur Communicative Development Inventories in term infants supplemented with formula containing DHA compared to control and DHA+AA formula groups, but not the human milk group. No effects of early DHA feeding on language were apparent at three years of age when children were tested again (Auestad et al., 2003). In a term study supported by Ross Laboratories, Auestad et al. (2001) found, in a randomized controlled trial among term infants, significantly higher vocabulary production in those fed DHA and AA from fish and fungal sources compared to DHA and AA from egg triglyceride (p<0.05). Neither group differed, however, from controls on this or any other MacArthur subscore.

At most, specific outcomes have been measured in only one or two individual trials and these have been measured at different ages. Even though numerous developmental outcomes have been identified that collectively suggest there are benefits associated with EPA/DHA supplementation, it is difficult to subject the studies in total to a systematic review, because of the differences in experimental design among the studies. The benefits of postnatal DHA supplementation for cognitive development need further study because of the heavy reliance on global assessments as outcomes and the limited employment of more specific developmental outcomes. Furthermore, the majority of trials stopped looking at development well before children

reached school age, when more sophisticated measures of cognitive function may be employed.

Allergy and Immunity

Reviews of the effects of fatty acid supplementation on immune function in the neonate have not provided strong support for beneficial effects (Calder et al., 2001; Field et al., 2001) (see Appendix Table B-1h). One human study showed positive effects of human milk and formulas containing DHA and AA compared to formulas without DHA and AA in the form of lower CD4RO+ immune cells and IL-10 cytokine production (Field et al., 2000). However, experimental studies of DHA-supplemented lactating women have not found any effect of supplementation on milk cytokines at intakes as high as 140 mg/day EPA and 600 mg/day DHA (Hawkes et al., 2002) or 3.7 g EPA/DHA from fish oil (28 percent EPA and 56 percent DHA) in a group selected to be at high risk for allergic disease (Denburg et al., 2005).

Summary of Evidence

The strongest evidence of benefit for postnatal DHA supplementation in formula-fed preterm and term infants is higher visual acuity, an outcome that has been measured repeatedly in clinical trials. In addition, some positive effects have been found on cognitive function in infancy and childhood in both experimental and observational studies and in relation to both pre- and postnatal DHA intake. Reviews that take into account all lines of evidence have concluded that omega-3 fatty acids can be beneficial to cognitive development (Cohen et al., 2005; McCann and Ames, 2005), whereas reviews that rely strictly on published results from experimental trials limited to global assessments of cognitive development, e.g., the MDI, do not offer strong support (Simmer, 2005; Simmer and Patole, 2005).

Results of some experimental trials suggest that postnatal DHA infant formula supplementation benefits cognitive function as well. Specific behavioral domains such as novelty preference and duration of looking are more related to later function than global tests of development (Carlson and Neuringer, 1999; Jacobson, 1999). Bryan et al. (2004) and Cheatham et al. (2006) postulate that benefits associated with postnatal infant formula supplementation may have been underestimated as a result of the emphasis on global tests of infant development as well as the paucity of outcomes measured in childhood.

Animal Studies

Results from animal studies indicate a possible role for the timing of exposure to DHA in development. These studies testing variable levels of brain DHA on neurotransmitters such as dopamine and serotonin (Delion et al., 1996; de la Presa Owens and Innis, 1999; Chalon et al., 2001; Kodas et al., 2004) and responses of these neurotransmitter systems in rodent and pig models suggest there is a critical window for brain DHA accumulation for some aspects of development and that behavior remains abnormal even when brain DHA is remediated well before testing (Kodas et al., 2004; Levant et al., 2004). These animal studies, although not the subject of this review, provide suggestive evidence that the presence of DHA could be critical during early periods of human brain development.

BENEFITS TO CHILDREN

The few studies that exist of EPA/DHA supplementation in children have focused on the potential for EPA/DHA to modify diseases, i.e., they have not been designed to evaluate if DHA is needed in healthy children after infancy for optimal neurological development or physiological function. The majority of studies in children relate to diseases and disorders that involve brain and behavior, especially attention deficit hyperactivity disorder (ADHD) or dyslexia, though one experimental study evaluated possible effects of supplementation on symptoms of allergy. Few randomized trials have been carried out to test whether EPA/DHA supplementation in children reduced symptoms of ADHD, and there is little evidence for benefits. Neither can any conclusions yet be drawn about the possible role of seafood or EPA/DHA supplementation in the prevention of asthma. There is interest in the clinical benefits of EPA/DHA in certain childhood diseases and it is being actively studied, but such therapeutic interventions are beyond the scope of this report (see Appendix Table B-1i and B-1j).

FINDINGS

1. Seafood is a nutrient-rich food that makes a positive contribution to a healthful diet. It is a good source of protein, and relative to other protein foods, e.g., meat, poultry, and eggs, is generally lower in saturated fatty acids and higher in the omega-3 fatty acids EPA and DHA as well as selenium;

2. The evidence to support benefits to pregnancy outcome in females who consume seafood or fish-oil supplements as part of their diet during pregnancy is derived largely from observational studies. Clinical trials and epidemiological studies have also shown an association between increased duration of gestation and intake of seafood or fish-oil supplements. Evidence

that the infants and children of mothers who consume seafood or EPA/DHA supplements during pregnancy and/or lactation may have improved developmental outcomes is also supported largely by observational studies;

3. Increased EPA/DHA intake by pregnant and lactating women is associated with increased transfer to the fetus and breastfed infant.

a. A number of observational studies show a positive association between maternal blood or breast milk DHA levels and a range of developmental outcomes in infants and children.

b. Two experimental studies of maternal EPA/DHA supplementation found cognitive benefits for the children when they were 4 or 5 years of age.

c. Because these two studies differed dramatically in timing of EPA/DHA supplementation (pre- and postnatally or postnatally), source (cod-liver oil or algal DHA), and amount (2 g or 200 mg EPA/DHA) and, likely, in usual seafood intake (Norway or US residents), insufficient data are available to define an ideal level of EPA/DHA intake from seafood in pregnant and lactating women;

4. A large number of experimental trials have provided DHA directly to human infants through infant formula and have found benefits for infant and child neurological development. These trials offer the best evidence that infants/children would benefit from increased DHA in breast milk and increased maternal seafood intake.

a. Visual acuity has been measured in the most trials and is increased by DHA supplementation, with preterm infants more likely to benefit than term infants.

b. Cognitive benefits of postnatal DHA supplementation with formula have also been found in infancy and early childhood. However, the number of trials has been limited and the specific outcomes varied, precluding a systematic review;

5. At present there is no convincing evidence that ADHD, other behavioral disorders, and asthma in children can be prevented or treated with seafood or EPA/DHA consumption.

Part II: Benefits for Prevention of Adult Chronic Disease

CARDIOVASCULAR DISEASE, CARDIOVASCULAR MORTALITY, AND ALL-CAUSE MORBIDITY AND MORTALITY

Most evidence for benefits of seafood consumption and EPA/DHA supplementation associated with coronary heart disease (CHD) mortality is inferred from interventional studies of populations at risk, observational studies in the general population, and mechanistic studies. Early investiga - tions of the association between diet and cardiovascular disease led to the recommendations to restrict dietary fat and cholesterol as a public health intervention to prevent CHD. However, subsequent observations suggest a more complex association between dietary fat intake and cardiovascular pathophysiology (Howard et al., 2006).

Cardiovascular Benefits to Specific Population Groups

Certain populations in the Mediterranean region consuming a diet relatively high in monounsaturated fat from olive oil enjoyed some of the lowest cardiovascular disease rates in the world. Another intriguing observa tion came from the comparison of Greenland Eskimo populations that had low mortality rates from CHD compared to the mainland Danish popula - tion, despite having a diet rich in fat (Bang et al., 1971). Bang et al. (1971) hypothesized that genetics, lifestyle, and the high content of EPA/DHA in the diet (which consisted primarily of fish, sea birds, seal, and whale) may account for the low cardiovascular mortality rate observed in this popula - tion. Plasma lipid patterns examined in this study showed that most types of lipids were decreased compared to a Danish cohort control and Eskimos living in Denmark ($p < 0.001$). Remarkably, the levels of pre- ″ lipoprotein ($p < 0.001$) and, consequently, plasma triglycerides ($p < 0.001$) were much lower among the Greenland Eskimos than the Danish controls. As a result of this and related studies, seafood consumption, including or even especially of seafood rich in fat, has received increased attention as a public health means to decrease the burden of cardiovascular disease.

Several observational studies have shown an inverse association between seafood consumption and the risk of cardiovascular disease, most probably due to reductions of sudden death (reviewed in Wang et al., 2006). Some studies, however, have not found a significant association between seafood consumption and cardiovascular disease. These discrepancies may be due to

differences among study populations and the type, amount, or preparation method of seafood consumed. For example, among studies reviewed, it has been hypothesized that the benefit of greater amounts of seafood may be more apparent in populations that have low seafood intakes and are at higher risk for cardiovascular disease (Marckmann and Gronbaek, 1999). Although initial studies suggested an optimal level of seafood consumption, more recent analyses have brought this observation into question and have suggested a more continuous association between seafood consumption and prevention of cardiovascular disease (p for trend = 0.03) (He et al., 2004b).

The possible mechanisms by which seafood or EPA/DHA supplements are cardioprotective include demonstrated antiarrhythmic, antithrombotic, antiatherosclerotic, and anti-inflammatory effects. Ismail (2005) and Calder (2004) linked the consumption of EPA/DHA to improved endothelial function, lower blood pressure, and lower fasting and postprandial triglyceride concentrations. Furthermore, populations and individuals who consume large amounts of seafood also tend to consume smaller amounts of alternative protein sources, such as beef, that are rich in saturated fats that are known to increase blood cholesterol levels and to elicit a proinflammatory state (Weisberger, 1997; Baer et al., 2004; Miller, 2005). Any one or a combination of these effects may explain the association between seafood intake and cardiovascular protection observed in some studies.

It is important to note that supplementation trials have been mostly conducted in individuals with existing cardiovascular disease for secondary prevention. Therefore, these findings are relevant to the progression of existing cardiovascular disease, but may not be relevant to the development of new cardiovascular disease in the general population, as these two processes may have different biological determinants. On the other hand, many observational studies of seafood consumption have been conducted in the general population and are relevant to primary prevention and the development of cardiovascular disease in the first place. Again, as determinants of cardiovascular disease development may be different from those of disease progression, the pertinence of these observational studies to secondary prevention is limited. These studies are, however, more informative than supplementation studies to assess the role of seafood in a healthy diet. The committee has tried to clearly differentiate these two types of studies and the conclusions that can be derived from them in the discussions that follow.

Seafood or Omega-3 Fatty Acid Consumption and Coronary Heart Disease

Randomized Controlled Trials in high Risk Populations

No randomized controlled trials have been carried out on subjects representative of the general population, as the small expected number of

cardiovascular events would require large and perhaps impractical sample sizes and/or follow-up periods. In an early randomized trial of men who had already experienced a myocardial infarction (MI), Burr et al. (1989) reported that dietary advice, including advice to increase consumption of seafood, was associated with a significant reduction (29 percent) in 2-year all-cause mortality ($p < 0.05$). An extended follow-up of these subjects, however, did not suggest any substantial long-term survival benefit (Ness et al., 2002). In contrast, in a separate study of male subjects over age 70 with stable angina, Burr et al. (2003) reported higher, and not lower, cardiovascular mortality in the group assigned to receive advice to consume seafood or n-3 fatty acid supplements (p=0.02). The reports by Burr et al. (2003) and Ness et al. (2002) seemed to some researchers a serious challenge to the idea that patients with coronary artery disease (CAD) and those at increased risk for heart disease should be advised to increase consumption of seafood rich in EPA/DHA or to take fish-oil supplements (Marckmann, 2003). A more detailed review of the literature considered by the committee is provided in Appendix B-2.

The Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto Miocardico (GISSI-Prevenzione) trial (GISSI Prevenzione Investigators, 1999) examined associations between dietary supplementation with EPA/DHA from fish oil, vitamin E, or combined treatment, and incidence of a second MI. From October 1993 to September 1995, 11,324 Italian patients surviving recent (δ 3 months) MI were randomly assigned supplements of EPA/DHA (1 g daily, n=2836), vitamin E (300 mg daily, n=2830), both (n=2830), or none (control, n=2828) for 3.5 years. The primary combined efficacy measurement endpoints of death, nonfatal MI, and nonfatal stroke were significantly reduced by EPA/DHA treatment; the relative risk reduction (RRR) was 15 percent for death, nonfatal MI, or nonfatal stroke (RR=0.85; 95% CI 0.74-0.98). Intention-to-treat analyses were done according to a (two-way) factorial design and by a (four-way) treatment group.

Results showed that EPA/DHA, but not vitamin E supplementation, significantly reduced risk of death, nonfatal MI, and nonfatal stroke (RR=0.90, 95% CI 0.82-0.99, two-way analysis; RR=0.85, 95% CI 0.74-0.98, four-way analysis). A decrease was found in the risk of all-cause mortality (14 percent [95% CI 3-24] two-way, 20 percent [95% CI 6-33] four-way) and cardiovascular death (17 percent [95% CI 3-29] two-way, 30 percent [95% CI 13-44] four-way). There was no significant effect between the combined treatment and EPA/DHA for the primary endpoints listed above. This study showed that dietary supplementation with fish oil as a source of EPA/DHA led to a statistically significant benefit in people with a history of MI; however, effects on fatal cardiovascular events require further exploration.

The percentage of patients who experienced at least one cardiac event (cardiac death, resuscitation, recurrent MI, or unstable angina) was 28 in

the EPA/DHA group and 24 in the corn oil (control) group. There was no significant difference in prognosis between the groups for either single or combined cardiac events. Total cholesterol concentrations decreased in both groups, although intergroup differences were not significant. On average, high density lipoprotein (HDL) cholesterol increased by 1.1 percent in the EPA/DHA group and by 0.55 percent in the corn oil group ($p=0.0016$) per month. In the same time period, triacylglycerol concentrations decreased by 1.3 percent in the EPA/DHA group, whereas they increased by 0.35 percent in the corn oil group per month ($p<0.0001$). Thus, no clear clinical benefit of a high-dose concentrate of EPA/DHA acids compared with corn oil was shown, despite a favorable effect on serum lipids.

In addition to the randomized clinical trials described above, another commonly cited study in support of the benefits of fish oil consumption comes from the Indian Study on Infarct Survival. This was reported by Singh et al. (1997) as a randomized, placebo-controlled study of 360 Indian patients enrolled within 1 day after MI into one of three groups: a group receiving fish oil (1.08 g/day EPA and 0.72 g/day DHA), a group receiving mustard seed oil (20.0 g/day, ALA content 2.9 g/day), and a placebo (control) group receiving aluminum hydroxide (100 mg/day). The combined primary end point was total cardiac events (sudden cardiac death plus total cardiac deaths plus nonfatal reinfarction). According to the authors, the fish oil group had a 30 percent lower risk in total cardiac events after 1 year, compared to the placebo group (RR=0.70; 95% CI 0.29-0.90). However, serious concerns have been raised about the performance and conclusions of this trial and other related publications from this investigator (White, 2005; Al-Marzouki et al., 2005) and therefore, based on these caveats, the evidence in support of EPA/DHA consumption should be considered after exclusion of this widely used report.

Taken together, these randomized trials showed conflicting results for an effect of EPA/DHA on cardiovascular events and no long-term protective effect of seafood intake in subjects with a previous history of CHD. These findings are consistent with a systematic Cochrane review that concluded that "It is not clear that dietary or supplemental omega-3 fats alter total mortality, combined cardiovascular events, or cancers in people with, or at high risk of, cardiovascular disease or in the general population" (Hooper et al., 2005) and with the more recent work of Hooper et al. (2006).

Observational Studies of Seafood or EPA/DHA Intake in the General Population

Several studies have addressed a possible association of seafood or EPA/DHA intake with cardiovascular deaths or events in the general population, including individuals with a previous history of CHD. Whelton et al. (2004)

conducted a meta-analysis of observational studies to determine if seafood consumption was associated with lower fatal and total CHD in people with and without a history of heart disease. The analysis included English-language articles published before May 2003. A total of 19 observational studies (14 cohort and 5 case-control) met the prestated inclusion criteria that the studies were conducted in adult humans, used an observational case-control or cohort design, compared a group that consumed seafood regularly with one that did not, used CHD as an outcome, and reported an association as a relative risk (RR), hazard ratio (HR), or odds ratio (OR) of CHD by category of seafood consumption. A random effects model was used to pool data from each study. The analysis found that regular fish consumption compared to little to no fish consumption was associated with a relative risk of 0.83 (95% CI 0.76-0.90; $p<0.005$) for fatal CHD and 0.86 (95% CI 0.81-0.92; $p<0.005$) for total CHD.

He et al. (2004b) also examined associations between seafood consumption and CHD mortality in people with or without a history of heart disease using a meta-analysis design. A database was developed based on 11 eligible studies that included 13 cohorts consisting of a total of 222,364 individuals and an average follow-up of 11.8 years. Pooled RR and 95 percent CI for CHD mortality were calculated by using both fixed-effect and random-effect models. Possible dose-response relationships were assessed using a linear regression analysis of the log RR weighted by the inverse of variance. The results of the analysis found a consistent inverse association between seafood consumption and CHD mortality rates and suggested a dose-response association. The pooled multivariate RRs for CHD mortality, compared to seafood intake less than once per month, were 0.89 (95% CI 0.79-1.01) for seafood intake one to three times per month, 0.85 (95% CI 0.76-0.96) for once per week, 0.77 (95% CI 0.66-0.89) for two to four times per week, and 0.62 (95% CI 0.46-0.82) for five or more times per week.

Each 20 g/day increase in seafood intake lowered the risk of CHD mortality by 7 percent (p for trend = 0.03). These results indicate that mortality from CHD may be significantly reduced by eating seafood as infrequently as once per week, with increasing benefit with increasing intake. This meta-analysis does not provide subgroup analyses and does not include case-control studies.

The most recent meta-analysis by König et al. (2005) provides another quantitative assessment of the association between seafood consumption and CHD. In this meta-analysis, all studies identified of primary prevention, i.e., incidence of CHD in people without a history of CHD, were observational studies that assessed seafood intake, while all studies of secondary prevention, i.e., in people with a history of CHD, were randomized trials using EPA/DHA supplements at doses difficult to achieve with seafood consumption. The authors of this meta-analysis were able to provide a

quantitative assessment of the association of seafood consumption with CHD mortality and nonfatal MI in people without a history of CHD, but concluded that insufficient evidence supported a quantitative assessment of seafood consumption for secondary prevention. From this study, it was estimated that, compared to not eating seafood, eating a small amount of seafood—as little as half a serving per week—was associated with a reduction in risk of cardiovascular death of 17 percent (95% CI 8.8-25.0) and a reduction in risk of nonfatal MI of 27 percent (95% CI 21-34). Each additional weekly serving of seafood was associated with a further decrease in the risk of cardiovascular death of 3.9 percent (95% CI 1.1-6.6), but no additional benefit was statistically significant for the risk of nonfatal MI. The Agency for Healthcare Research and Quality (AHRQ) reviews are systematic reviews that synthesize observational and experimental studies in a qualitative way (see Appendix B). The conclusions of the AHRQ reviews are also based on intervention studies in groups at risk. In contrast, the studies by Whelton et al., He et al., and Konig et al. are meta-analyses that quantitatively combined observational studies. Meta-analyses are usually considered stronger evidence than systematic reviews.

Taken together, these meta-analyses of observational studies suggest a negative association between seafood consumption and CHD or death, particularly in individuals without a prior history of CHD. Recent data suggest that even small amounts of seafood consumption may be associated with a decreased risk for CHD or death (Schmidt et al., 2005a,b). These results should, however, be interpreted with caution, as they are based on observational studies and are thus subject to residual confounding. In other words, based on observational studies only, it is difficult to exclude the possibility that seafood intake may just be a marker for healthier lifestyle, and that no causal association exists between seafood consumption and cardiovascular protection (see Appendix Tables B-2a and B-2b).

Stroke

The only reported studies of the association between seafood consumption and stroke have been observational (see Appendix Table B-2b). He et al. (2004a) quantitatively assessed the relationship between seafood consumption and risk of stroke using a meta-analysis of nine cohorts from eight studies. Pooled RR and 95 percent CI of risk for stroke were estimated by variance-based meta-analysis. These results demonstrated that consumption of seafood was inversely related to stroke risk, particularly ischemic stroke. Even infrequent seafood consumption (as seldom as 1 to 3 times per month) may be protective against the incidence of ischemic stroke compared to seafood consumption less than once per month. The pooled RRs for *all* stroke, compared to individuals who consumed seafood less than once a month,

were 0.91 (95% CI 0.79-1.06) for individuals with seafood intake one to three times/month, 0.87 (95% CI 0.77-0.98) for once/week, 0.82 (95% CI 0.72-0.94) for two to four times/week; and 0.69 (95% CI 0.54-0.88) for five or more times/week (p for trend = 0.06).

Three large cohort studies with data on stroke subtypes were used in a stratified meta-analysis to determine pooled RRs across five categories of seafood intake for ischemic stroke. Compared to individuals who consumed seafood less than once a month, the RRs were 0.69 (95% CI 0.48 -0.99) for individuals with seafood intake one to three times/month, 0.68 (95% CI 0.52-0.88) for once/week, 0.66 (95% CI 0.51-0.87) for two to four times/week; and 0.65 (95% CI 0.46-0.93) for five or more times/week (p for trend = 0.24) (He et al., 2004a).

For hemorrhagic stroke, compared to individuals who consumed sea - food less than once a month, the RRs were 1.47 (95% CI 0.81-2.69) for individuals with seafood intake one to three times/month, 1.21 (95% CI 0.78-1.85) for once/week, 0.89 (95% CI 0.56-1.40) for two to four times/ week, and 0.80 (95% CI 0.44-1.47) for five or more times/week (p for trend = 0.31) (He et al., 2004a). In a separate recent meta-analysis, Bouzan et al. (2005) quantified the association of seafood consumption with stroke risk, based on five cohort studies and one case-control study. Although a decrease of 12 percent in the risk of both ischemic and hemorrhagic strokes was observed with a small amount of seafood consumption compared to no seafood consumption, this result was not statistically significant (95%CI: increased risk of 1 percent to decreased risk of 25 percent). Furthermore, there was no evidence for further decrease in the risk of strokes with in - creasing seafood intake above a small amount: 2 percent decrease in risk per serving per week (95%CI: increased risk of 2.7 percent to decreased risk of 6.6 percent).

Skerrett and Hannekens (2003) reviewed ecologic/cross-sectional and case-control studies of associations between consumption of seafood or EPA/DHA and stroke risk. Five prospective studies showed inconsistent results: no association, a possible inverse association, and three significant inverse associations. In the most recent Nurses' Health Study, the relative risk for total stroke was somewhat lower among women who regularly ate seafood compared to those who did not, although there was no significant difference. After adjusting for age, smoking, and other cardiovascular risk factors, a significant decrease in the risk for thrombotic stroke was observed among women who ate seafood at least two times per week compared with those who ate seafood less than once per month (RR=0.49; 95% CI 0.26-0.93). The decrease observed among women in the highest quintile of EPA/DHA intake was not significant nor was an association observed between consumption of seafood or fish oil and hemorrhagic stroke.

Data from Mozaffarian et al. (2005) suggest that the type of seafood

meal may be an influential variable. Mozaffarian and collaborators investigated the association between seafood consumption and stroke risk in the Cardiovascular Health Study, an older population in whom the disease burden is high. Dietary intakes were assessed in 4775 adults aged ε65 years (range, 65–98 years) and free of known cerebrovascular disease at baseline in 1989–1990 using a food frequency questionnaire. In a subset of this population, consumption of tuna or other broiled or baked seafood, but not fried seafood or fish sandwiches (fish burgers), correlated with plasma phospholipid long-chain omega-3 fatty acid levels. During 12 years of follow-up, participants experienced 626 incident strokes, of which 529 were ischemic strokes. Tuna/other seafood consumption was associated with a 27 percent lower risk of ischemic stroke when consumed one to four times per week (HR=0.73; 95% CI 0.55-0.98), and with a 30 percent lower risk when consumed five or more times per week (HR=0.70, 95% CI 0.50-0.99) compared with consumption of less than once per month.

Conversely, consumption of fried fish/fish sandwiches was associated with a 44 percent higher risk of ischemic stroke when consumed once per week compared with less than once per month (HR=1.44; 95% CI 1.12-1.85). Seafood consumption was not associated with hemorrhagic stroke. Consumption of tuna or other broiled or baked seafood was associated with lower risk of ischemic stroke while intake of fried seafood/fish sandwiches was associated with higher risk among elderly individuals.

Taken together, these observational studies provided inconclusive results for an association between seafood intake and stroke. These results suggest that seafood consumption may influence stroke risk; however, identification of mechanisms or alternate explanations for the results requires further study. The type of seafood meal, particularly the method of preparation, is not recorded in most observational studies but may be a major effect modifier.

Lipid Profiles

The effects of seafood or EPA/DHA on serum lipid profiles have been extensively studied to determine if intake influences indicators of cardiovascular disease risk (see Appendix Table B-2c). In AHRQ Evidence Report/Technology Assessment No. 93 (2004), Balk et al. showed that with few exceptions, serum triglyceride levels were found to decrease with increasing intake of EPA/DHA, and this change was statistically and biologically significant. Moreover, the effect appears to be dose-dependent regardless of the EPA/DHA source. Most of the studies reviewed reported net decreases of approximately 10–33 percent in triglyceride levels. Effects were dose-dependent among subjects that were healthy, had cardiovascular disease, or

were at increased risk for cardiovascular disease or dyslipidemia, and were greatest among subjects who had higher mean baseline triglyceride levels.

EPA/DHA intake was only weakly associated with levels of other serum lipids, including total, high-density lipoprotein (HDL), and low-density lipoprotein (LDL) cholesterol and lipoprotein (a) (Lp(a)). Balk et al. (2004) reviewed 65 randomized controlled trials and found a wide range of effects of EPA/DHA on total cholesterol. Most studies achieved a small net effect and the trend was towards increased total cholesterol; however, the direction of the effect was not consistent across studies. For example, two studies (Hanninen et al., 1989; Mori et al., 1994) used seafood-based diets as part of the intervention protocol, and neither of them reported significant effects of seafood consumption on total cholesterol levels. Further, Mori et al. (1994) found that LDL cholesterol levels were not changed in subjects consuming EPA/DHA-enriched diets. No significant differences were found in men who consumed various doses of EPA and DHA either from seafood or fish oil.

Balk et al. (2004) reviewed 19 reports of effects of EPA/DHA on HDL cholesterol. Most studies reported small increases in HDL cholesterol, and in about one-third of the studies, the effects were statistically significant. One study conducted in men using intervention with a seafood-enriched diet (Mori et al., 1994) found no difference among those consuming various doses of EPA and DHA either as supplements or from seafood in a diet regimen. In a randomized controlled trial, Vandongen et al. (1993) found that the effect of EPA/DHA on HDL cholesterol was independent of the source of the EPA/DHA.

Consistent effects of EPA/DHA on Lp(a) levels have not been found (Balk et al., 2004). In approximately one-third of the 14 studies reviewed, EPA/DHA intakes were associated with a net increase in Lp(a) compared to controls. In the remaining studies reviewed, the net decrease in Lp(a) level was generally small and nonsignificant. Only two studies (Eritsland et al., 1995; Luo et al., 1998) reported a statistically significant difference between the effect of EPA/DHA intake and control. Both found a net decrease in Lp(a) ($p=0.023$; only for those with a baseline Lp(a) of $\varepsilon 20$ mg d/l). However, the large interindividual variability in Lp(a) levels resulted in wide confidence intervals in all studies reviewed by Balk et al. (2004). One study examined a diet enriched with seafood, but found no significant effect on Lp(a) levels (Schaefer et al., 1996).

Blood Pressure

Increased consumption of seafood is one of several dietary recommendations in studies examining dietary effects on blood pressure. Thus, the

effect of EPA/DHA from seafood is difficult to isolate from benefits provided by other dietary changes.

Randomized Controlled Trials

The effect of fish-oil supplementation has been studied in a meta-analysis of experimental studies (Geleijnse et al., 2002). The overall results of 36 trials examined indicate that the mean adjusted net reduction in systolic and diastolic blood pressure was –2.1 mmHg (95% CI –3.2 to –1.0), and –1.6 mmHg (95% CI –2.2 to –1.0), respectively. Moreover, systolic and diastolic blood pressure reductions were significantly greater in older (mean age ε45 years) than younger populations, and in hypertensive (blood pressure ε140/90 mmHg) compared to normotensive populations. Inconsistent results among studies in women precluded adequate analysis based on sex. Body mass index, trial duration, and seafood dose did not affect the blood pressure response noted with fish-oil supplementation. Studies conducted in diabetic patients were not included in the meta-analysis. The review by Balk et al. (2004) found only small and inconsistent net effects of EPA/DHA on blood pressure levels of diabetic patients.

A single RCT with advice to increase seafood intake has been reported. The Diet and Reinfarction Trial (DART) examined the effect of advice to consume seafood on blood pressure outcomes at 6 and 24 months in over 2000 men with a history of MI (Ness et al., 1999). The average intake of the group advised to consume fish was 330 mg of EPA compared to 100 mg in the control group. There were no significant differences in blood pressure detected between the groups at either 6 or 24 months.

Observational Studies

Appleby et al. (2002) examined the effect of diet and lifestyle factors on differences between meat eaters, seafood eaters, vegetarians, and vegans on the prevalence of self-reported hypertension, and mean systolic and diastolic blood pressure. Data for the analysis was obtained from the Oxford cohort of the European Prospective Investigation into Cancer and Nutrition (EPIC-Oxford). More than 11,000 adult men and women were classified into the four diet groups for analysis. Results showed that age-adjusted prevalence of self-reported hypertension in men was 15 percent in meat eaters, 9.8 percent in both seafood eaters and vegetarians, and 5.8 percent in vegans. In women, the prevalence was 12.1, 9.6, 8.9, and 7.7 percent in the respective diet groups. After adjustment for body mass index (BMI), the group differences decreased in both men and women. When seafood eaters were compared to vegetarians, no benefit was seen that could be attributed to seafood consumption per se.

Dewailly et al. (2001) examined the relationship between plasma phospholipid concentrations of EPA/DHA and various cardiovascular disease risk factors among the Inuit of Nunavik, Canada, whose traditional high-seafood diet contains very large amounts of EPA/DHA. Over 400 Inuit adults participated in a health survey that included home interviews and clinical visits. Plasma samples were obtained from participants and analyzed for phospholipid fatty acid composition. No association was found between phospholipid content of EPA/DHA and blood pressure in this population of high seafood consumers.

It is unclear from these studies whether seafood consumption, in the range consumed by most Americans, is an effective means to reduce blood pressure (see Appendix Table B-2d). Further, it is not known if the association between EPA/DHA consumption and blood pressure is linear or if there is a threshold below which no benefit is detectable.

Arrhythmia

Leaf et al. (2003) reviewed studies of prevention of arrhythmic deaths correlated with EPA/DHA intake, summarizing clinical evidence for the antiarrhythmic effect of EPA/DHA and reviewing possible mechanisms of action through modulation of ion channels in cardiomyocytes. Based on the evidence from human and experimental data (see Appendix B-2e) the authors suggest that in the presence of family history of sudden cardiac death, supplementation with EPA and DHA should be of 1 to 2 grams/day.

Christensen et al. (1999) examined the effect of EPA/DHA on heart rate variability in healthy subjects by randomized controlled trial. Treatment groups received either low- or high-dose EPA/DHA from fish-oil supplements and control groups received olive oil for 12 weeks. No significant effect of the fish-oil supplements was found on heart rate variability. In an earlier study, Christensen et al. (1996) examined the effect of EPA/DHA supplementation on subjects who had a recent MI and found significant improvement in heart rate variability among the fish-oil supplemented group ($p=0.04$); however, when those subjects were segregated by level of seafood consumption (Christensen, 1997), the groups who consumed one or more seafood meals per week had somewhat higher heart rate variability that was not statistically significant.

More recently, Frost and Vestergaard (2005) examined the association between consumption of EPA/DHA from fish and risk of atrial fibrillation or flutter on the prospective cohort study of 47,949 participants (mean age: 56 years) in the Danish Diet, Cancer, and Health Study. During a follow-up of 5.7 years, atrial fibrillation or flutter had developed in 556 subjects (374 men and 182 women). Using the lowest quintile of omega-3 fatty acid intake from fish as a reference, the unadjusted hazard rate ratios in quintiles 2–5

were 0.93 (95% CI 0.70-1.23), 1.11 (95% CI 0.85-1.46), 1.10 (95% CI 0.84-1.45), and 1.44 (95% CI 1.12-1.86), respectively (p for trend=0.001). The corresponding adjusted hazard rate ratios were 0.86 (95% CI 0.65-1.15), 1.08 (95% CI 0.82-1.42), 1.01 (95% CI 0.77-1.34), and 1.34 (95% CI 1.02-1.76) (p for trend = 0.006). In conclusion, there was no association between n-3 fatty acid intake from fish and a reduction in risk of atrial fibrillation or flutter. Surprisingly, the risk was significantly higher at increased EPA/DHA intake. The authors, however, were unable to exclude the possibility of residual confounding caused by a lack of information on intake of fish-oil supplements.

Other Cardiovascular Indicators

Fibrinogen

Balk et al. (2004) found no consistent effect of EPA/DHA on fibrinogen levels, and the studies reviewed were equally divided among those showing increases, no change, or decreases in fibrinogen levels compared to controls. Most of the study results were not significant. However, for those that did show statistically significant differences between omega-3 treatment and controls, three showed decreases ranging from 5–20 percent, and one showed an increase of 11 percent in fibrinogen levels. Cobiac et al. (1991) reported that seafood consumption may be associated with a small decrease in fibrinogen level (change = 0.15 ± 0.12), which was significantly different than the change in the controls ($p < 0.05$). Overall, however, no significant differences in effect of EPA/DHA on fibrinogen level have been shown (see Appendix Table B-2f).

Clotting Factors

Most studies reviewed by Balk et al. (2004) found a net decrease in von Willebrand factor with increased EPA/DHA intake. However, only one study reported statistical significance in the association. None of the studies reviewed examined the effects of regular consumption of seafood meals on von Willebrand factor levels.

Other clotting factors were also reviewed by Balk et al. (2004). Factor VII showed no consistency in effects across studies, with equal numbers of subjects reporting increases and decreases of factor VII activity in relation to EPA/DHA intake. Agren et al. (1997) reported that the effects of EPA/DHA levels from seafood consumption were not significant and were similar to those observed for fish-oil supplementation and an algal source of DHA oil supplementation in the same study. Findings from studies on EPA/DHA on factor VIII are similar to those for factor VII with some studies showing

a net increase and others a net decrease. None of the studies investigated specify the effect of increased seafood consumption on factor VIII levels (Balk et al., 2004) (see Appendix Table B-2f).

Platelet Aggregation

Platelet aggregation is a very complex measurement, depending on the aggregating agent, the dose of the agent, and the measurement metric used. As a result, findings of studies on the effects of EPA/DHA on platelet aggregation are inconsistent and difficult to interpret (Balk et al., 2004). Agren et al. (1997) examined the effects of a seafood-based diet, fish-oil supplementation, and algal DHA oil on platelet aggregation and showed that collagen aggregation was reduced more in subjects on both the seafood diet and fish-oil supplementation regimens, but not the algal DHA oil treatment, compared to the controls ($p < 0.05$). No significant association was found for EPA/DHA impairment of platelet aggregation, although algal DHA oil is less potent than either fish oil or seafood (which are sources of both EPA and DHA) (see Appendix Table B-2f).

Indicators of Glucose Tolerance in Diabetes

Although EPA/DHA consumption has been shown to improve lipid profiles and other indicators of cardiovascular risk in those with type II diabetes, there is currently no evidence that intakes of 2–4 g/day of EPA/DHA can improve glycemic control (Grundt et al., 1995; Sirtori et al., 1998; Kesavulu et al., 2002). Consistent with this finding, a review (Balk et al., 2004) concluded that there was no clear evidence that EPA/DHA had an effect on moderating glucose tolerance or hemoglobin A_{1c} levels, fasting blood sugar, and fasting insulin levels (see Appendix Table B-2g).

Allergy and Asthma

The Nurses' Health Study's prospective cohort was evaluated by Troisi et al. (1995) for a possible association of risk for adult-onset asthma and frequency of intake of various types of food. A semi-quantitative food frequency questionnaire was employed to index food intake over the previous year (e.g., "dark meat" seafood vs. other seafood). Over 1200 cases of adult-onset asthma were identified. Data from this study showed that the 6-year risk of adult-onset asthma was unrelated to the frequency of intake of dark meat seafood, tuna, or shrimp. This nonsignificant association was maintained when results were adjusted for age and smoking status, and also when other factors (body mass index, residential area, number of physician visits, and energy intake) were adjusted for (see Appendix Table B-2h; see also Schachter et al., 2004, AHRQ Report No. 91).

Cancer

The biological functions associated with consumption of omega-3 fatty acids suggest that it may have some impact on cancer risk (Larsson, 2004). Available evidence comes primarily from observational studies rather than randomized controlled trials (Terry, 2003; MacLean, 2006) (see Appendix Table B-2i; see also MacLean et al., 2005b, AHRQ Report No. 113). A small number of these studies show some protection for certain types of cancer (i.e., breast, colorectal, and lung), whereas others support an increase in risk (e.g., breast). The majority of the studies, however, conclude there is no significant effect on risk for cancer associated with seafood consumption or intake of other sources of EPA/DHA. Overall, the consumption of seafood, ALA, or EPA/DHA from all sources does not appear to decrease cancer risk (MacLean, 2006).

Aging and Other Neurological Outcomes

Consumption of EPA/DHA, specifically from seafood consumption, may provide some protection in terms of age-related cognitive decline as well as risk for Alzheimer's and other neurological diseases (Kalmijn et al., 1997; Gharirian et al., 1998; Barberger-Gateau et al., 2002; Morris et al., 2003). It should be noted that, as discussed above for cancer, evidence for reduced risk for these diseases comes primarily from observational studies. The beneficial effects appear to be more closely related to the consumption of seafood and/or global intake of DHA rather than EPA or ALA. Overall, the evidence is tenuous and counterbalanced by a number of studies that did not find significant benefits (see Appendix Table B-2j; see also MacLean et al., 2005a, AHRQ Report No. 114).

Summary of Evidence

Results from individual studies are not consistent and results from critical reviews are not clearly supportive of a cardioprotective effect of EPA/DHA. Furthermore, evidence for an effect on other adult chronic disease is controversial. Tables that summarize the committee's assessment of levels of evidence and reports from individual studies are shown in Table 3-2 and Appendix Tables B-1 through B-2. The level of evidence identified as "Contradictory or insufficient evidence to base recommendations" includes outcomes where a large body of literature exist, but leads to contradictory conclusions, as well as outcomes where the body of literature is too small to lead to recommendations. The committee's assessment of level of evidence summarized in Table 3-2 has its limitations. The Oxford Centre for Evidence-based Medicine's levels of evidence may not be ideal to assess nutrition studies. The quality of the various studies cannot be summarized

TABLE 3-2 Level of Evidence for Benefits of Increasing Seafood or EPA/DHA Intake in the General Population [a] and Specific Subgroups Reviewed

Level of Evidence [b]		Higher Seafood Intake	Increase in EPA/DHA Intake
1a	Meta-analyses of randomized controlled trials		• Blood pressure • Triglyceride levels • Infant neurological development
1b	Randomized controlled trial(s)		• Gestational duration • Mortality and cardiovascular events in people with a history of MI • Infant neurological development
2a/3a	Meta-analyses of observational studies	• Cardiovascular mortality and events	
2b	Cohort study(ies)	• Fetal neurological development • Gestational duration • Postpartum depression in women	
3b	Case-control study(ies)		
	Cross-sectional study(ies)		
	Contradictory evidence or insufficient evidence on which to base recommendations	• Blood pressure • Stroke • Allergy and asthma • Cancer • Alzheimer's disease • Glycemic control in type II diabetes	• Cardiovascular mortality and events • Arrhythmia • Cancer • Alzheimer's disease • Glycemic control in type II diabetes • Allergy and asthma • Preeclampsia • Postpartum depression • HDL, LDL, Lp(a) levels

[a] Unless otherwise noted.

[b] The level of evidence is based on the Oxford Centre for Evidence-based Medicine's Levels of Evidence (http://www.cebm.net/levels_of_evidence.asp#top). When several levels of evidence existed, only the highest level of evidence was reported.

using this approach, but is described in more detail in the preceding discussions. Furthermore, the committee's selection of studies reflects its subjective assessment of quality and importance, and is therefore subject to limitations. Only the highest level of evidence is provided in the table, and studies with a lower level of evidence are omitted. For an alternative approach to the assessment and synthesis of evidence, refer to the recent and comprehensive

AHRQ systematic reviews addressing these questions (Balk et al., 2004, AHRQ Report No. 93; Jordan et al., 2004, AHRQ Report No. 92; MacLean et al., 2004, AHRQ Report No. 89; Schachter et al., 2004, AHRQ Report No. 91; Wang et al., 2004, AHRQ Report No. 94; MacLean et al., 2005b, AHRQ Report No. 113; MacLean et al., 2005a, AHRQ Report No. 114.)

FINDINGS

1. Observational evidence suggests that increased seafood consumption is associated with a decreased risk of cardiovascular deaths and cardiovascular events in the general population. Evidence is insufficient to assess if this association is mediated through an increase in EPA and DHA consumption and/or a decrease in saturated fat consumption and/or other correlates of seafood consumption.

2. Experimental studies of the effect of EPA/DHA supplements on cardiovascular mortality or cardiovascular disease have not been conducted in the general population.

3. There is mixed evidence suggesting that consumption of fish-oil supplements for individuals with a history of MI will protect them from further coronary events. Meta-analyses have also led to mixed conclusions, with most recent analyses suggesting no benefits. Experimental evidence from in vitro and other types of mechanistic studies suggests that EPA/DHA intake should be associated with positive cardiovascular outcomes. However, this prediction has not been borne out in results of human studies.

4. In the general population, the effect from increased seafood consumption on the lipid profile is unclear. However, experimental studies of EPA/DHA supplementation at levels >1 g per day showed decreased triglyceride levels; the effect on other components of the lipid profile is less clear.

5. Evidence is inconsistent for protection against further cardiovascular events in individuals with a history of myocardial infarction from consumption of EPA/DHA-containing seafood or fish-oil supplements. The protection evidenced by population (observational) studies has not been consistently observed in randomized clinical trials.

6. Evidence for a benefit associated with seafood consumption or fish-oil supplements on blood pressure, stroke, cancer, asthma, type II diabetes, or Alzheimer's disease is inconclusive. Whereas observational studies have suggested a protective role of EPA/DHA for each of these diseases, supportive evidence from randomized clinical trials is either nonexistent or inconclusive.

7. Based on the three recent meta-analyses of observational studies (Table 3-2), there appears to be a linear association between seafood consumption and primary prevention of cardiovascular disease; the committee did not find strong scientific evidence to suggest a threshold of consumption,

such as two servings per week, below which seafood consumption provides no benefit and above which increasing consumption provides no additional benefits.

RECOMMENDATIONS

Recommendation 1: Dietary advice to the general population from federal agencies should emphasize that seafood is a component of a healthy diet, particularly as it can displace other protein sources higher in saturated fat. Seafood can favorably substitute for other high biologic value protein sources while often improving the overall nutrient profile of the diet.

Recommendation 2: Although advice from federal agencies should also support inclusion of seafood in the diets of pregnant females or those who may become pregnant, any consumption advice should stay within federal advisories for specific seafood types and state advisories for locally caught fish.

RESEARCH RECOMMENDATIONS

Pregnant and Lactating Women

Recommendation 1: Better data are needed to determine if outcomes of increasing consumption of seafood or increasing EPA/DHA intake levels in US women would be comparable to outcomes of populations in other countries. Such studies should be encouraged to include populations of high fish-consumers outside the United States to determine if there are differences in risks for these populations compared to US populations.

Recommendation 2: Dose-response studies of EPA/DHA in pregnant and lactating women are needed . This information will help determine if higher intakes can further increase gestation duration, reduce premature births, and benefit infant development. Other studies should include assessing whether DHA alone can act independently of EPA to increase duration of gestation.

Infants and Toddlers

Recommendation 3: Research is needed to determine if cognitive and developmental outcomes in infants are correlated with performance later in childhood. This should include:

- Evaluating preschool and school-age children exposed to EPA/DHA in utero and postnatally, at ages beginning around 4 years when executive function is more developed, and;

- Evaluating development of school-age children exposed to variable EPA/DHA levels in utero and postnatally with measures of distractibility, disruptive behavior, and oppositional defiant behavior, as well as more commonly assessed cognitive outcomes and more sophisticated tests of visual function.

Recommendation 4: Additional data is needed to better define optimum intake levels of EPA/DHA for infants and toddlers.

Children

Recommendation 5: Better-designed studies about EPA/DHA supplementation in children with behavioral disorders are needed.

Adults at Risk for Chronic Disease

Recommendation 6: In the absence of meta-analyses that systematically combine quantitative data from multiple studies, further meta-analyses and larger randomized trials are needed to assess outcomes other than cardiovascular, in particular total mortality, in order to explore possible adverse health effects of EPA/DHA supplementation.

Recommendation 7: Additional clinical research is needed to assess a potential effect of seafood consumption and/or EPA/DHA supplementation on stroke, cancer, Alzheimer's disease, and depression.

Recommendation 8: Future epidemiological studies should assess intake of specific species of seafood and/or biomarkers, in order to differentiate the health effects of EPA/DHA from those of contaminants, such as methylmercury.

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4

Health Risks Associated with Seafood Consumption

This chapter reviews the potential risks associated with chronic exposure to particular seafoodborne contaminants and risks associated with certain more acute seafoodborne hazards. The discussion includes consideration of the extent to which seafood consumption might increase consumers' risk of adverse health impacts due to exposure to toxicants, depending upon the critical dose-response relationships for the contaminant, the distribution of contaminant body burden in the population, and the extent to which the body burden is due to seafood consumption rather than to other sources and pathways of exposure. The chapter concludes with a discussion of the interaction between nutrients and contaminants—in particular, selenium and methylmercury—in seafood, and measures that consumers can take to reduce exposure to contaminants that may be present in seafood.

ENVIRONMENTAL CHEMICALS

Consumers seeking the health benefits associated with the consumption of seafood are concerned about potential health risks associated with the presence of chemical contaminants, both those occurring naturally and those resulting from human activities, in seafood. These contaminants include inorganic compounds such as methylmercury and other metals, as well as persistent organic pollutants (POPs) such as dioxins and polychlorinated biphenyls (PCBs). Of these, methylmercury is the contaminant that has elicited the most concern among consumers.

Methylmercury

Mercury is a heavy metal that is present in the environment as a result of both human activities (referred to as anthropogenic sources) and natural processes. The primary anthropogenic source is the combustion of fossil carbon fuels, particulary from coal-fired utility boilers; other sources include municipal, medical, and hazardous waste incineration (NRC, 2000). The natural sources include volcanic emissions and the weathering of rock containing mercury ore. Mercury can be deposited locally or travel long distances in the atmosphere and contaminate sites far from its point of release. Further, the complex biogeochemistry of mercury fate and transport creates uncertainty in efforts to apportion the relative contributions of these processes to global mercury pollution. The US Environmental Protection Agency (US EPA) estimated that 50 to 75 percent of the total yearly input of mercury into the environment is anthropogenic (US EPA, 1997), while the United Nations Environment Programme (UNEP) suggests that this source accounts for more than half of the inputs (UNEP, 2002).

Mercury exists in the environment in several different forms, including metallic, inorganic, and organic, and interconversion between forms can occur. The form of mercury of greatest concern with regard to seafood consumption is methylmercury (MeHg). Methylmercury results when mercury in other forms is deposited in water bodies and biotransformed through the process of methylation by microorganisms. It bioaccumulates up the aquatic trophic food chain as smaller organisms are consumed by larger organisms. Because methylmercury is persistent, this bioaccumulation process results in large long-lived predatory species, such as certain sharks, swordfish, and tuna, or freshwater species such as bass, walleye, and pickerel having the highest concentrations (Kraepiel et al., 2003). Methylmercury levels can also be high in marine mammals such as whales, and in animals that feed on marine life, such as polar bears and sea birds. Consumption of aquatic life is the major route of human exposure to methylmercury. The seafood choices a consumer makes, and the frequency with which different species are consumed, are thus important determinants of methylmercury intake. Because of the global dispersion of methylmercury and migration of species, the extent of regional variation in body burdens among different aquatic animals is less striking than the regional variations in certain other water contaminants, such as PCBs or dioxin-like compounds (DLCs). This implies that the location in which an aquatic animal was caught might provide relatively little information about its methylmercury content.

Methylmercury is not lipophilic (lipid soluble) and is thus present in the largest concentrations in the muscle tissue of aquatic animals rather than in fat or oils. Approximately 95 percent of ingested methylmercury is absorbed across the gastrointestinal tract into the blood. The half-life

of methylmercury in blood in humans is estimated to be 50 days, and the whole-body half-life to be 70–80 days, although the residence time of mercury in the brain appears to be considerably longer (NRC, 2000). Hair is frequently used as an exposure biomarker for methylmercury. Hair is a route of methylmercury excretion, and approximately 80 to 90 percent of the total mercury found in hair is in the methylated form. Hair mercury is a good biomarker in fish-consuming populations. Autopsy studies suggest that maternal hair mercury level correlates reasonably well with the level of mercury in the fetal brain (Cernichiari et al., 1995).

Mercury Burdens in the US Population

The first nationally representative estimates of blood and hair mercury levels were provided by the National Health and Nutrition Examination Survey (NHANES) of 1999–2000. Among women 16–49 years old, the geometric mean hair mercury level was 0.2 parts per million (ppm), with 75th, 90th, and 95th percentiles of 0.42, 1.11, and 1.73 ppm, respectively (McDowell et al., 2004). The geometric mean blood mercury level was 1.02, with 75th, 90th, and 95th percentiles of 2.07, 4.84, and 7.13 ppm, respectively (Mahaffey et al., 2004). The prevalence of levels in excess of 5.8 ∝g/L (benchmark dose lower bound [BMDL] adjusted for uncertainty and for population variability) was 5.66 percent. Levels were 50 percent higher among older women (30–49 years) compared to younger women, and levels were highest among women who self-identified as "Other" racial/ethnic category (Asians, Native Americans, Pacific Islanders). Mercury burdens were strongly associated with the amount of self-reported fish consumption (Mahaffey et al., 2004). Among women reporting eating 5–8 fish meals per month, these figures were 2.56, 4.54, 8.80, and 11.60 ppm, respectively. Levels were seven times greater among women who reported eating nine or more fish meals in the previous 30 days, compared to women who reported no consumption. Among these relatively high fish-consumers, the 50th, 75th, 90th, and 95th percentiles for blood mercury were 3.02, 6.68, 12.00, and 13.40 ppm, respectively.

Data on blood and hair mercury levels in adult men in the United States were not collected as part of NHANES until 2003, and no data for this group has been reported. Therefore, estimates must be made based on mercury biomarker data reported as part of large cohort studies. Urine and blood mercury levels of 1127 Vietnam-era pilots were measured for a study of the health effects of exposure to dental amalgam (Kingman et al., 1998). The mean blood mercury level in this group of men was 3.1 ppm, with a range up to 44 ppm, but the contribution of fish consumption to blood mercury levels is unknown because data were not collected on fish intake.

An important limitation of NHANES as a source of data on population exposures to methylmercury is that the sampling plan used to identify the 3637 women who contributed data in the 1999–2002 survey is likely to have missed subgroups of high fish-consumers, including sport fishers and subsistence fishers. Examples of such groups include individuals living in areas that provide ready access to seafood (e.g., island populations) (Ortiz-Roque and Lopez-Rivera, 2004), fishers (Burge and Evans, 1994; Bellanger et al., 2000), groups for whom fish or marine mammals are an especially important component of overall diet, and individuals who consume a high-fish diet for its cardioprotective effects. For example, one report described a case series of 116 patients who consumed large quantities of fish and had their blood tested; almost all (89 percent) had blood mercury levels greater than 5 ∝g/L, ranging up to 89∝g/L (Hightower and Moore, 2003). Evidence from the Third National Report on Human Exposure to Environmental Chemicals (CDC, 2005b) suggests that population exposures to mercury might have decreased between 1999–2000 and 2001–2002. Among women 16–49 years of age, the geometric mean declined from 1.02 ∝g/L (95% CI 0.825-1.270) to 0.833 (95% CI 0.738-0.940). An even greater decline was evident at the high end of the distribution, as the level corresponding to the 95th percentile in the earlier survey was 7.10 (95% CI 5.30-11.30) compared to 4.6 (95% CI 3.7-5.9) in the later survey. Because of the short time period covered by these data, however, the possibility that the observed time trend reflects sampling variability cannot be rejected.

health Effects in Critical Target Organs

Organs of the central nervous and cardiovascular systems are consid - ered to be the critical target organs with regard to methylmercury.

Neurological Toxicity The tragic epidemic of frank neurological disease that was identified in the late 1950s in Minamata, Japan, first brought to the world's attention the devastating effects of methylmercury on the developing fetal brain. Children exposed in utero to high levels of MeHg presented with cerebral palsy, mental retardation, movement and coordination disorders, dysarthria, and sensory impairments.The neuropathological lesions associated with Congenital Minamata Disease (mercury poisoning) were diffuse, occurring throughout the brain. In individuals exposed only in adulthood, the lesions were highly focal, clustering in regions that matched clinical presentation (e.g., motor disorders = precentral gyrus and cerebel - lum, constriction of visual fields = calcarine fissure of occipital cortex). The major molecular mechanisms of MeHg neurotoxicity include inhibition of protein and macromolecular synthesis, mitochondrial dysfunction, defective calcium and ion flux, disruption of neurotransmitter homeostasis, initiation

of oxidative stress injury, microtubule disaggregation, and post-translational phosphorylation (Verity, 1997). The diffuse injury associated with prenatal exposure is attributable to the ability of MeHg to arrest mitotic cells in metaphase, disrupting the exquisitely choreographed processes of cell proliferation, differentiation, and migration. The result is a brain in which there are reduced cortical cell densities, islands of heterotopic neurons in cerebral and cerebellar white matter, anomalous cytoarchitecture, disturbance in laminar pattern of cerebral cortex, absence of granule and Purkinje cells in the cerebellum, incomplete myelination in the hypoplastic corpus callosum, glial proliferation ("bizarre astrocytes in the white matter"), and limited gyral differentiation (Choi, 1989).

No cases of Congenital Minamata Disease have been reported in the United States, where the primary concern has been whether chronic exposure to MeHg, as the result of seafood consumption among the general population, is associated with subtle adverse health outcomes. Therefore, several risk assessments have been conducted in the past decade in which the goal was to identify a fetal mercury burden that can be interpreted as being without appreciable risk. The basis for most risk assessments for MeHg exposure has been one or more of the three major epidemiologic studies available: the New Zealand study (Kjellstrom et al., 1986), the Faroe Islands study (Grandjean et al., 2001), and the Seychelles study (Myers et al., 2003) (see Box 4-1).

The New Zealand and Faroe Islands studies, but not the Seychelles study, have generally been regarded as providing evidence of harm from MeHg exposures at which clinical effects are not evident, although it should be noted that benchmark dose analyses of the data from the 9-year evaluation of children in the Seychelles study cohort produced BMDLs in the range of 17–23 ppm (Van Wijngaarden et al., 2006), only slightly higher than the BMDLs based on the New Zealand and Faroe Islands studies data. In view of the perceived discrepancies in the findings of the three studies, the choice of critical study has stimulated considerable controversy. Some risk assessors chose the Faroe Islands study (US EPA, 2001; NRC, 2000), while others chose the Seychelles study (ATSDR, 1999). In an effort to use all of the best available data, the Joint Expert Committee on Food Additives and Contaminants (JECFA), a joint committee of the World Health Organization (WHO) and the Food and Agricultural Organization of the United Nations (FAO), averaged the effect estimates reported for the Faroes and Seychelles studies; including the New Zealand study did not significantly change the results (FAO/WHO JECFA, 2003). In all these assessments, however, the final result was a single number interpreted as a reference level for intake for the most sensitive subgroup, the fetus, as shown in Table 4-1. These reference levels differ largely because of differences in the uncertainty factors applied. These levels were derived on the basis of health effects observed, rather than

BOX 4-1
Three Major Epidemiological Studies on Methylmercury

These three studies were conducted among geographically disparate island populations with a high availability of seafood (tuna is an important export product of Seychelles, approximately one-third of the Faroese workforce is employed in the fishing industry, and both aquaculture and marine fishing feature in the economy of New Zealand). Cohen (2004) summarized these three cohorts in reviews.

Seychelles Child Development Study

The Seychelles Child Development Study (SCDS) is an ongoing collaboration between the Ministry of Health of Seychelles, a small archipelago country in the Indian Ocean, and the University of Rochester, New York. "Initially the objectives focused on two primary questions. Firstly, could clinical neurodevelopment effects be found in children after exposure to methylmercury (MeHg) in utero from a maternal diet high in fish and, secondly, what is the lowest level of foetal [*sic*] exposure to cause such effects?" (Shamlaye, 2004). Seychelles was determined to be a favorable location for this study for a number of reasons: the Seychellois regularly consume fish (an average of 12 meals per week), and the number of annual births allowed for recruitment of a large cohort of mothers and children in a short period of time (Shamlaye, 2004; Myers et al., 2003). The Seychelles Child Development Study enrolled 779 mother-infant pairs between 1989 and 1990, of which 717 were eligible for analysis. Among the tests administered at 107 months were the Wechsler Intelligence Scale for Children—Third Edition, the Boston Naming Test, the California Verbal Learning Test, the Bruininks-Oseretsky Test of Motor Proficiency, a Continuous Performance Test, the Developmental Test of Visual-Motor Integration, the Grooved Pegboard, and selected subtests of the Woodcock-Johnson Tests of Achievement. The children were evaluated (i.e., cognitive, language, motor, adaptive behavior, and social-emotional development) at 6, 19, 29, 66, and 107 months. Maternal hair samples were also collected at enrollment. The information provided here, along with the results from the study, can be accessed in the Special Issue of the *Seychelles Medical and Dental Journal,* Volume 7, Issue 1, 2004. [Online]. Available: http://www.seychelles.net/smdj/ [accessed July 7, 2005]. Also, in 2000, Clarkson et al. recruited a new cohort of mother-infant pairs in Seychelles, and this project is due for completion in 2006.

Faroe Islands Study

The Faroe Islands Study, conducted in this North Atlantic Ocean archipelago located between Scotland, Norway, and Iceland, consisted of a cohort of

1022 consecutive singleton births from 1986–1987. The objective of this study was to investigate possible neurobehavioral effects of prenatal exposure to neurotoxicants, such as methylmercury. The Faroese are high consumers of seafood, including pilot whale, which exposes them to high levels of methylmercury. The study team analyzed maternal hair mercury concentrations and cord blood mercury concentrations at birth and conducted neurobehavioral examinations on 917 of the children just before school entry (about 7 years of age) and at 14 years of age. The detailed examinations, which lasted about 5 hours for each child, took place mostly in the National Hospital in Torshavn, the capital of the Faroes Island. The examination included finger tapping; hand-eye coordination; reaction time on a continuous performance test; Wechsler Intelligence Scale for Children—Revised Digit Span, Similarities, and Block Design; Bender Visual Motor Gestalt Test; Boston Naming Test; and California Verbal Learning Test. The parent accompanying the child (usually the mother) was also asked to fill out a self-administered questionnaire on the child's past medical history, current health status, and social factors (Grandjean, 1997).

New Zealand Study

The New Zealand Study involved the screening of 11,000 children born in 1978, over 900 of whose mothers consumed fish more than four times per week during pregnancy. As with the other cohorts, the objective of this study was to investigate the association between prenatal mercury exposure and subsequent development during childhood (Crump, 1998). Maternal hair samples were collected at birth to assess mercury exposure during pregnancy. At 4 years of age, the Denver Developmental Screening Test and a set of neurological screening tests were completed on 74 children, 38 with "high" maternal hair mercury levels (> 6µg/g) and 36 with "low" maternal hair mercury levels, matched on maternal demographic characteristics, age, hospital where the birth took place, and date of birth. Maternal interviews about the ages at which the child achieved developmental milestones were also conducted (Kjellstrom et al., 1986). At 6 years of age, 238 children were evaluated. A child with a high maternal hair mercury was matched with three children with low hair mercury levels, but similar in gender, maternal ethnic group, age, smoking habits, location of residence, and number of years living in New Zealand (Kjellstrom et al., 1989). The tests administered included the Test of Oral Language Development, the Weschlar Intelligence Scale for Children-Revised, and the McCarthy Scales of Children's Abilities.

TABLE 4-1 Reference Levels for Fetal Exposure to Methylmercury

Source	Reference Level
JECFA provisional tolerable weekly intake	1.6 μg/kg body weight/week
US EPA reference dose	0.1 μg/kg body weight/day
Agency for Toxic Substances and Disease Registry minimal risk level	0.3 μg/kg body weight/day

SOURCES: FAO/WHO JECFA, 2003; US EPA, 2001; ATSDR, 1999.

the general population, and are risk management guidelines rather than estimates of threshold of effect. While such numbers can be used to estimate the number of individuals at potential risk (i.e., for whom the margin of exposure is less than 10-fold), they convey nothing about the quantitative characteristics of the dose-response relationship, i.e., for the risk associated with each unit increase in mercury burden above the reference level.

A variety of hypotheses have been proposed to explain the apparent discrepancy between the results of the Seychelles and Faroe Islands studies. The National Research Council (NRC) committee did not consider that any of them is clearly supported by the evidence, however. The issues evaluated include differences between populations in the temporal characteristics of exposure (presumed to be stable among the Seychellois, but potentially episodic among the Faroese due to occasional consumption of pilot whale), reliance on different biomarkers of exposure (cord blood mercury vs. maternal hair mercury), population differences in vulnerability to methylmercury, the influence of other aspects of nutrition on methylmercury toxicity, and differences in the neuropsychological tests administered and the ages at which children were assessed. Consideration has also been given to the possibility of residual confounding in one or both studies, particularly with regard to the high exposures of the Faroese to PCBs and other POPs.

Although considerable debate has ensued seeking to identify the reasons for the apparent discrepancies among the three major studies of fetal MeHg neurotoxicity, their magnitude might be less dramatic than commonly supposed. As the analyses of the National Research Council Committee on the Toxicological Effects of Methylmercury showed, the BMDLs calculated for the three major studies vary by much less than the 10-fold (one order of magnitude) uncertainty factor applied to the BMDL to achieve the Reference Dose (RfD) (NRC, 2000). Figure 4-1 shows a qualitative effort to assess the degree of concordance among studies of the "no observed adverse effect levels" (NOAEL) estimated for each study on the basis of benchmark dose analysis. An estimate of 10 to 20 ppm appears to be reasonably accurate. Interestingly, this is the range identified by WHO (1990) based solely on the relatively poor-quality data available from a mass poisoning episode

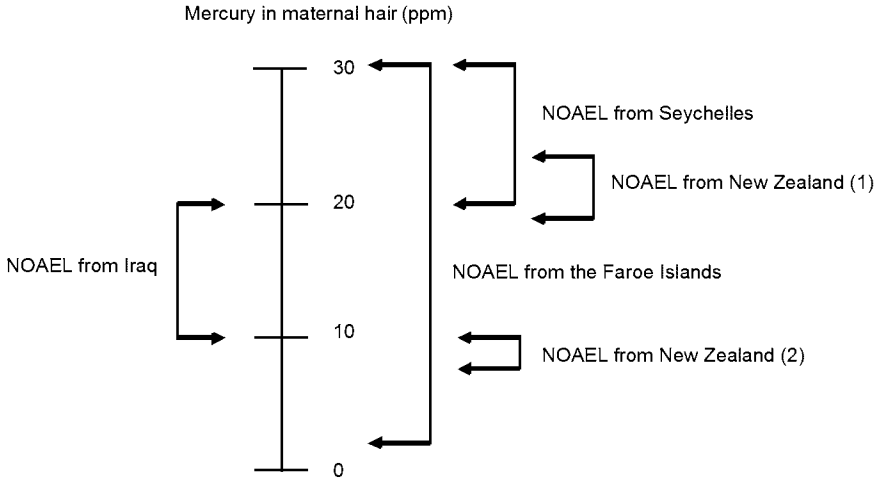

FIGURE 4-1 Integration of data from the New Zealand, Faroe Islands, and Seychelles studies of prenatal methylmercury neurotoxicity. Two ranges are provided for the NOAEL from the New Zealand study. The estimate labeled (1) was derived when the data for a child with a very high maternal hair mercury level (86 ppm) were included in the analyses. The estimate labeled 2 was derived when the data for this child were excluded. This child's mercury level was more than fourfold higher than the level for any of the 236 other children in this cohort.
NOTE: NOAEL = No observed adverse effect level.
SOURCE: Personal communication, Clarkson et al., University of Rochester, March 2005.

that occurred in Iraq in the 1970s (Personal communication, Clarkson and colleagues, University of Rochester, March 2005).

Ryan (2005) conducted an analysis of data from the three previously described studies using maximum likelihood and Bayesian hierarchical models to derive an estimate of the slope of the dose-response relationship between children's neurodevelopment and their prenatal methylmercury exposure. This analysis, presented to the Committee on Nutrient Relationships in Seafood (Ryan, 2005), suggested that children's IQ scores decline by 0.1 to 0.25 points for each ppm increase in maternal hair mercury level. The point estimates were nearly identical in the three studies (results for the New Zealand study differed considerably depending on whether one particular observation was included or excluded) (see Figure 4-2).

The point estimates of the slopes for the other neurodevelopmental endpoints measured in the three studies, some of which were common across studies, were also surprisingly similar (Figure 4-3).

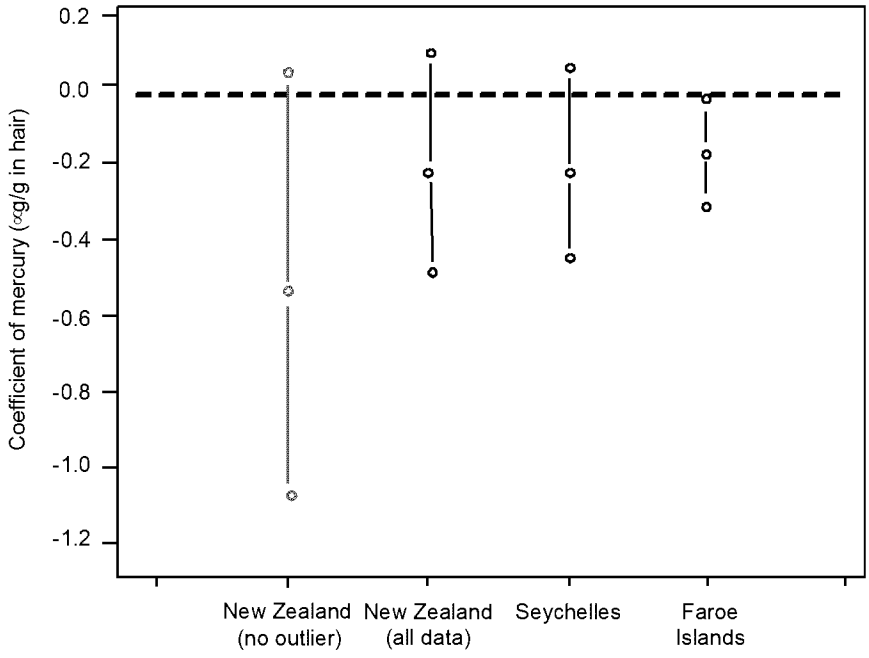

FIGURE 4-2 Point estimates and 95 percent confidence intervals, based on regression analyses, for the changes in full scale IQ ("coefficients") associated with each ppm increase in maternal hair mercury reported in the three studies. A coefficient with a negative sign indicates that the IQ scores for children within a study cohort decreased with increasing hair mercury level. Two estimates are provided for the New Zealand study, one based on the inclusion of the child with a maternal hair mercury level of 86 ppm and one based on the exclusion of this child.
SOURCE: Ryan, 2005.

These analyses, therefore, suggest that although the findings of the Seychelles study appear discrepant from those of the Faroe Islands and New Zealand studies if one focuses only on the p-values of the reported analyses, at a deeper, quantitative level that focuses on the rates of decline in scores as mercury burden increases, the findings of the three studies are remarkably concordant.

Part of the challenge in characterizing the health risks associated with increased MeHg exposure in seafood is related to the fact that this source also provides nutrients that might have health effects which mitigate those of MeHg. Thus, studies tend not to provide a "pure" estimate of MeHg toxicity but an estimate that represents the balance between the putative harm caused by the contaminant and the putative benefits provided by the

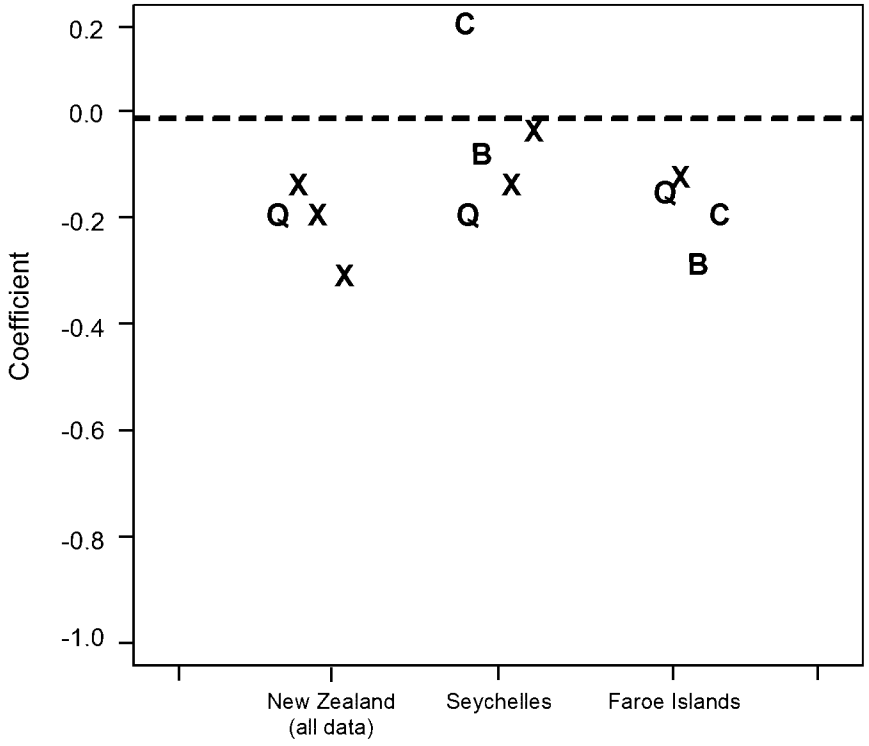

FIGURE 4-3 Coefficients for achievement and cognition-related endpoints from the three studies. The symbols Q, C, and B denote the three endpoints that are common to two or more studies, namely IQ (Q), California Verbal Learning Test (C), and Boston Naming Test (B), respectively. X's indicate endpoints that were unique to one of the studies. Coefficients reflect the change in test score for each ppm increase in maternal hair mercury. A coefficient with a negative sign indicates that a test score decreased as maternal hair mercury level increased. New Zealand estimates are based on including the child with a maternal hair mercury level of 86 ppm. The Faroe Islands median hair:cord blood ratio of 200 (Budtz-Jorgensen, 2004b) was used to convert the Faroe Islands results to units of hair mercury.
SOURCE: Ryan, 2005.

nutrients in seafood. This issue is critical, however, because the goal in giving advice regarding seafood consumption should be to enable people to obtain the greatest benefit for the least risk.

An illustration of the delicacy of this balance is provided by a study of 135 mother-infant pairs in Boston (Oken et al., 2005). Mothers reported consuming an average of 1.2 fish servings per week during the second trimester of pregnancy (range 0–5.5 servings/week), and had a mean hair

mercury level at delivery of 0.55 ppm (range 0.02–2.38; 10 percent had levels >1.2 ppm). At 6 months of age, infants' scores on a visual recognition memory task were positively associated with maternal fish intake during the second trimester (4 points for each additional weekly serving), but inversely associated with maternal hair mercury level (7.5 points per ppm). Performance was best among infants whose mother consumed more than two servings of fish per week but whose hair mercury level was less than 1.2 ppm. This study was designed as a study of nutrition rather than of methylmercury intake, however, so women were asked about their fish intake using categories (canned tuna, shellfish, "dark meat" fish, other fish) that relate more directly to omega-3 fatty acid levels than to MeHg levels (see Box 3-1).

Data germane to the balance between the benefits and risks associated with consumption of fish and development in children were also reported from the Avon Longitudinal Study of Parents and Children (ALSPAC), a large ongoing birth cohort study in the UK (Daniels et al., 2004). In a subsample of 1054 of 10,092 eligible children, associations were evaluated between maternal fish consumption during week 32 of gestation, reported on a food frequency questionnaire, and maternal reports of children's language development at 15 months and general development at 18 months. The categories used in collecting data on the types of fish consumed were "white fish" (cod, haddock, plaice, fish sticks, etc.) and "oily fish" (pilchards, sardines, mackerel, tuna, herring, kippers, trout, salmon, etc.). Most women (88 percent) reported eating fish during pregnancy. Of these, 65 percent reported eating fish from both categories. Unfortunately, this way of classifying fish results in groupings that differ from those that would result if classification were based on mercury levels. Overall, children's developmental abilities, as reported by mothers, increased modestly with increased maternal fish intake during pregnancy. Most of the benefit appeared to be associated with any fish consumption, compared to none, as maternal consumption of fish more than one to three times per week did not seem to confer additional benefits, at least with regard to the child development outcomes assessed. Higher mercury concentration in umbilical tissue, for which the median was 0.01 ∝g/g wet weight, was not associated with adverse developmental outcomes in children, although cord tissue mercury is not a well-established biomarker of exposure. Cord mercury level did increase across strata of maternal fish intake, although the greatest increase was between the "none" and "1 per 2 weeks" strata, with little increase evident in the two strata representing greater fish intake ("1–3 per week" and "4+ per week") (see Box 3-1).

Jensen et al. (2005) reported that the usual substantial neuropsychological benefits associated with breastfeeding were not evident among the children in the Faroe Islands cohort. The authors speculated that contaminants pres-

ent in the breast milk of the Faroese women mitigated the benefits to their children.

Increasing attention is being paid to the neurotoxicities observed in adults exposed to MeHg, although the findings are mixed and do not support firm conclusions about the dose-response/dose-effect relationships. In a small case series report, patients who were clinically referred for paresthesias, in 50 percent of whom mixed peripheral neuropathy with axonal loss was confirmed by electrodiagnostic studies, blood mercury levels ranged from 27 to 96 μg/L (Saint-Phard et al., 2004). Most of the patients reported consuming fish at least twice weekly. These blood mercury levels are considerably higher than those of the general US population. As noted earlier, the geometric mean among US women of child-bearing age is 0.833 μg/L (95% CI 0.738-0.94). In a study involving 129 residents of Brazilian fishing communities, in whom the mean hair mercury level was 4.2 μg/g (range 0.56–13.6), dose-dependent reductions in performance on tests of fine motor speed, dexterity, and concentration were found (Yokoo et al., 2003). In reanalyses of data from a 1977 study of 366 Québec Cree (First Nation) adults, Auger et al. (2005) reported that a 6 ppm increase in hair mercury level was associated with an odds ratio of 2.2 (95% CI 1.15-4.26) for tremor in a proportional odds ordinal regression model. Scalp hair mercury levels ranged from 0.5 to 46.1 ppm. Blood mercury level (mean 37.7 μg/L, range 1–150) was not associated with an increased risk of tremor, however. In a cross-sectional study of 106 elderly (ε 75 years) Swedes with mercury levels of 2–80 nmol/L (mean 17, standard deviation 11; values for 101 subjects were δ28 nmol/L), blood mercury level was not associated with scores on the Mini-Mental Status Examination (Johansson et al., 2002). In the only large study conducted on US adults, among 474 adults aged 50 to 70 years, blood mercury level (median 2.1 μg/L; range 0–16) was not consistently associated with performance on a battery of 12 neuropsychological tests (Weil et al., 2005).

Cardiovascular Toxicity The hypothesis that elevated exposures to methylmercury might impair cardiovascular health was suggested by a series of observational studies conducted by Finnish investigators. Men with the highest level of hair mercury (>2 μg/g) had a twofold increase in risk (95% CI 1.2-3.1) (adjusted for age, examination year, ischemic exercise electrocardiogram (ECG) and maximal oxygen uptake) of an acute (fatal or nonfatal) myocardial infarction (MI) and had a 2.3-fold increased risk (95% CI 0.9-5.8) (adjusted for age, examination year, ischemic exercise ECG and maximal oxygen uptake) of death from coronary heart disease (CHD) (Salonen et al., 1995). In addition, self-reported fish consumption of 30 g per day or more was associated with a doubling of risk of an acute MI. Mercury burden was more strongly related to the amounts of nonfatty

freshwater fish (turbot, vendace, northern pike, whitefish) consumed rather than fatty fish (salmon, herring, domestic rainbow trout, tuna) (Salonen et al., 1995). Follow-up examinations of this cohort conducted 4 years later indicated that high hair mercury level at baseline was a significant predictor of the increase in the common carotid intima-media thickness (IMT), suggesting accelerated carotid atherosclerosis (Salonen et al., 2000). Among men in the highest quintile of hair mercury level (>2.81 ppm), the IMT increase was 32 percent greater than among men in the rest of the cohort. The increased cardiovascular risk associated with higher fish consumption reported by Salonen et al. (1995, 2000) and Virtanen et al. (2005) might, for example, be associated with food preparation techniques (see Chapter 5) rather than methylmercury levels in the fish consumed by Finnish men, although this variable was not addressed in these reports.

In a case-control study conducted in nine countries involving 684 men less than 70 years of age with a first diagnosis of MI (Guallar et al., 2002), the adjusted (including docosahexaenoic acid [DHA]) odds ratio for men in the highest, compared to the lowest, quintile of toenail mercury level was 2.16 (95% CI 1.09-4.29). Adjusting for toenail mercury level, the risk of MI was inversely related to adipose tissue DHA level (OR=0.59, 95% CI 0.30-1.19, for highest vs. lowest quintile).

In contrast to the findings of the Finnish studies and the Guallar et al. (2002) study, essentially null findings were reported in a nested case-control study of toenail mercury levels (an alternative biomarker) and coronary heart disease (coronary artery surgery, nonfatal MI, fatal coronary heart disease) in 33,737 male health professionals (Yoshizawa et al., 2002). In the highest, compared to the lowest, quintile of mercury level, the relative risk of coronary heart disease was 0.97 (95% CI 0.63-1.50). Adjustment for omega-3 fatty acid intake did not alter this. A major uncertainty about the interpretation of these two studies is the status of toenail mercury level as a biomarker of mercury burden attributable to fish consumption. In the Yoshizawa et al. study, more than half of the study cohort consisted of dentists, and the mean toenail mercury level in dentists was more than twice the mean among the nondentist health professionals. Although toenail mercury level was modestly correlated with reported fish consumption (correlation of 0.42), toenail mercury level apparently also reflects exposures to mercury from nonfish sources, such as elemental mercury from dental amalgams and dental amalgam preparation. In this regard, it is noteworthy that when the dentists were excluded from analyses in the Yoshizawa et al. (2002) study, increased toenail mercury was associated with increased risk of coronary heart disease. The increase in risk was not statistically significant, however, at least in part because of the reduced sample size.

As noted, because the primary vehicle in which methylmercury is delivered is a food that also contains nutrients that might have health effects

that are antagonistic to those of methylmercury, it is difficult to obtain "pure" estimates of methylmercury toxicities. For example, a follow-up study of the Finnish men reported on by Salonen et al. (1995) showed that men in the highest quintile of docosapentaenoic acid and docosahexaenoic acid intake, compared to men in the lowest quintile, had a 44 percent lower risk of CHD over a 4-year period (Rissanen et al., 2000). Analyses stratified by hair mercury level suggested, however, that the reduction was greater (52 percent) for men with hair mercury (Hg) levels <2 ppm than among men with hair Hg levels >2 ppm (only 24 percent). A similar shift in the balance of the risks of methylmercury and the benefits of omega-3 fatty acids was found in a study of blood mercury level and blood pressure among US women (NHANES 1999–2000; Vupputuri et al., 2005). In the entire cohort of 1240 women aged 16–49 years, blood mercury level was not significantly associated with either systolic or diastolic blood pressure. When analyses were stratified by reported fish intake (759 consumers, 481 nonconsumers), systolic blood pressure increased significantly with blood mercury level among nonconsumers, corresponding to an approximately 5 mmHg difference between the lowest quintile (0.1–0.4 μg/L) and the highest quintile (2.1–21.4). Among the fish-consumers, systolic blood pressure declined (nonsignificantly) with increasing blood mercury level. The findings were similar for changes in diastolic blood pressure with increasing blood mercury level. Overall, this pattern suggests that increased exposure to mercury, obtained from sources other than fish consumption, is associated with higher blood pressure. When mercury exposure occurs in conjunction with fish consumption, however, the effects on blood pressure are blunted and, at the levels in most US women, may be counteracted by protective factors in fish. This interpretation is consistent with the null findings of a study of hair mercury levels and blood pressure in fish-consuming Indian tribes of the Amazon rain forest (Dorea et al., 2005).

Methylmercury Reference Dose

A report from the National Research Council of the National Academies reviewed the US EPA's process in deriving the RfD (see Box 4-2). It concluded that the existing RfD of 0.1 μg/kg per day was a "scientifically justifiable level for the protection of public health," although it recommended that it be derived on the basis of the findings of the newer epidemiological studies rather than of the Iraqi study (NRC, 2000). Such a calculation is subject to numerous uncertainties, however. Among these are the choice of the functional form of the statistical model used to identify the methylmercury dose at which a doubling of the target response occurs (e.g., linear vs. supralinear vs. sublinear models), the choice of the adverse health effect, the choice of the point estimate for the excess prevalence to be prevented,

BOX 4-2
Reference Dose for Methylmercury

The US Environmental Protection Agency (US EPA, 2001) established a Reference Dose (RfD) for methylmercury (MeHg) that it defines as "…an estimate of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." To derive the RfD for MeHg, the US EPA applied benchmark dose modeling. In this approach, the benchmark dose (BMD) is identified at which the prevalence of a defined health abnormality exceeds the background prevalence of the abnormality by a specified amount. The abnormality can be defined distributionally (e.g., scores more than 2 standard deviations below the mean) or clinically (e.g., the presence of a particular abnormal finding on neurologic examination). Once the critical dose is identified, the dose corresponding to the lower bound of its 95 percent confidence interval (the Benchmark Dose lower bound [BMDL]) is taken as the "point of departure" for calculating the Hg intake that would result in that dose. In other words, the BMDL is the lowest hair mercury (Hg) level that is statistically consistent with the observed increased in the prevalence of the target outcome. Although the US EPA used the Boston Naming Test results from the Faroe Islands study to illustrate the process by which it derived the RfD for Hg, it considered all of the data from the Faroe Islands and New Zealand studies and an integrative analysis that included the Seychelles study. A test score at the 5th percentile or below was selected as the critical health effect, and a doubling of the prevalence of such scores to be prevented (Rice, 2004). The US EPA selected 12 ppm in maternal hair as the critical BMDL (or 58 µg/L in cord blood). A one-compartment pharmacokinetic model, involving assumptions about factors such as the elimination constant, blood volume, MeHg absorption, fraction of absorbed dose in the blood, and the ratio of cord blood mercury to maternal blood mercury, was used to determine that an MeHg intake of 0.1 µg/kg/day over a lifetime would not result in a hair Hg level exceeding 1.2 ppm.

the choices of the point estimates for the assumptions made in fitting the one-compartment model, and the size of the aggregate uncertainty factor that should be applied to take account of all these unknowns (Rice, 2004). Reference Dose calculations are sensitive to the assumptions made about factors such as the ratio of cord blood Hg:maternal blood Hg. Although the RfD is intended to address a pregnant woman's MeHg intake, the fetal risk estimates for the Faroe Islands study, the critical study, were expressed as

cord blood Hg levels. The US EPA assumed a ratio of 1:1, but recent Monte Carlo analyses suggest that the Hg level in cord blood might be as much as 70 percent higher than the Hg level in maternal blood (Stern and Smith, 2003). The results of these analyses suggest that reducing the RfD so that maternal blood Hg levels do not exceed 3.4 μg/L would prevent cord blood Hg levels from exceeding 5.8 μg/L.

The NRC (2000) study identified several other important data gaps that contribute to uncertainty, e.g., the possibility of interindividual variation in susceptibility to MeHg. Factors that might affect susceptibility include age, sex, genetics, health status, nutritional status, and toxicokinetic and toxicodynamic processes. The role of nutritional factors as potential confounders or effect modifiers of MeHg neurotoxicity is particularly important (Chapman and Chan, 2000). The many differences between the diets of the Faroese and Seychellois have been suggested as a possible explanation for apparent differences between findings. The specific dietary components suggested as possibly important are DHA, iodine, choline, and iron (Clarkson and Strain, 2003). One study found that greater consumption of tropical fruit is associated with lower hair Hg levels, although it could not be determined whether this reflected altered absorption, distribution, or excretion (Passos et al., 2003). Other data gaps pertain to the lack of information about possible late-emerging neurodevelopmental effects as children mature and the lack of dose-response analyses for other potential adverse health effects of MeHg, such as cardiovascular disease. A third class of data gaps pertains to the characterization of exposure. Factors that contribute to this are a lack of dietary intake data, the extrapolation from a biomarker such as maternal hair Hg to maternal MeHg intake, confounding by coexposures to other neurotoxic contaminants (e.g., PCBs), and the impracticality of characterizing short-term temporal variations in exposure using currently available biomarkers, particularly during potentially critical windows of brain vulnerability. Using bootstrap analyses, Budtz-Jorgensen et al. (2004b) showed that the BMDL is overestimated by 25 percent if it is not adjusted for error in measuring cord blood Hg and by 40 percent if it is not adjusted for error in measuring hair Hg. The authors argued that a failure to take these sources of error into account would result in a reference dose that is too high, and thus insufficiently protective.

Summary of Evidence

Interpretations of data from the three major epidemiologic methylmercury studies are not entirely concordant. The Faroe Islands and New Zealand studies are regarded as providing evidence that children prenatally exposed to methylmercury as the result of maternal seafood consumption during pregnancy are at increased risk of manifesting subtle neurodevelopmental

deficits. The Seychelles study is regarded as not providing such evidence. A new statistical approach revealed similarities between the three studies not previously evident in published analyses. Results of this approach reduced the degree of discordance, which might have been overestimated due to a focus on p-values. This yielded greater consistency between findings of the three studies, indicating a decline of 0.1 to 0.25 points, on a scale of IQ-like measurement, for each part-per-million increase in maternal hair mercury level during pregnancy.

Observational studies in adult men from the general population have produced mixed results regarding the associations between fish consumption, mercury level, and cardiovascular health. Overall, the data considered suggests an increased risk of myocardial infarction among men with higher hair Hg levels. For both child neurodevelopment and adult cardiovascular health, emerging evidence suggests that the health benefits of seafood consumption are greater among individuals whose body burden of methylmercury is lower.

Other Metals

Metal contaminants other than mercury, including lead, manganese, chromium, cadmium, and arsenic may be present in seafood, although on a population basis, seafood consumption does not appear to be a major route of exposure to these metals. In analyses of farmed Atlantic and wild salmon, Foran et al. (2004) found that for none of nine metals measured did the levels exceed federal standards. For three of the metals measured (cobalt, copper, and cadmium), levels were significantly higher in wild than farmed salmon. Burger and Gochfeld (2005) measured the levels of seven metals (arsenic, cadmium, chromium, lead, manganese, mercury, selenium) in fish obtained from New Jersey markets. Although these levels sometimes exceeded health-based standards, the intercorrelations among the different metals were low, leading the authors to conclude that consuming a variety of fish species will reduce a consumer's risk. The source of fish is an important consideration, however. Kong et al. (2005) found levels of lead and chromium in farmed tilapia from China that exceeded local guidelines.

Persistent Organic Pollutants

Persistent organic pollutants are defined as organic chemicals that remain intact in the environment for long periods, become widely distributed geographically, bioaccumulate up the food chain by amassing in fatty tissues of animals, and are toxic to humans, wildlife, and the environment (Bidleman and Harner, 2000; IOM, 2003; UNEP Global Environmental Facility, 2003; Robson and Hamilton, 2005). Many POPs are chlorinated

compounds, but brominated and fluorinated compounds also exist (e.g., brominated flame retardants and Freon) and may have a detrimental impact on the environment.

Evidence for long-range transport (to regions distant from the original source) and the threats posed to the environment (Fries, 1995a,b; UNEP Global Environmental Facility, 2003) has prompted regulatory action to reduce emissions (CFSAN, 2001; also reviewed in IOM, 2003). As a result of concerns about global circulation through the atmosphere, oceans, and other pathways, the US signed an agreement on POPs at a diplomatic conference in Stockholm, Sweden (UNEP Global Environmental Facility, 2003). Under this Convention, signatory countries were committed to reduce and/or eliminate the production, use, and/or release of the 12 POPs of greatest concern to the global community and to establish a mechanism by which additional chemicals may be added to the treaty in the future. The POPs initially targeted by the agreement, informally called the "dirty dozen" (Table 4-2), include:

- Certain insecticides, such as DDT and chlordane, once commonly used to control pests in agriculture and building materials;
- Polychlorinated biphenyls, used in electrical, heat transfer, and hydraulic equipment and as plasticizers in paints, plastics, and rubber products;
- Certain chemical byproducts, such as dioxins and furans, which are produced unintentionally from most forms of combustion, including municipal and medical waste incinerators, open barrel burning, and industrial processing.

The POPs to which seafood consumers are most likely exposed are the dioxins, dioxin-like compounds (DLCs), and PCBs.

Dioxins and Dioxin-like Compounds

Dioxins and DLCs are unintentional by-products of combustion of organic material. Sources of dioxins include herbicides (2,4,5-T), wood preservatives, diesel and gasoline fuel combustion, and industrial combustion and backyard barrel burning. Currently, new dioxin releases into the environment are mostly from backyard and agricultural burning (IOM, 2003). Because of the long half-life of dioxins, they will persist in the environment. Furthermore, even if all anthropogenic sources could be eliminated, low levels of naturally occurring dioxins will continue to be produced (US EPA, 2003).

Since 1987, the US EPA has been taking action to effectively reduce environmental release of dioxins and furans to land, air, and water from

TABLE 4-2 The "Dirty Dozen" Identified in United Nations Environment Programme

The "Dirty Dozen"
Aldrin[a]
Chlordane[a]
DDT[a]
Dieldrin[a]
Endrin[a]
Heptachlor[a]
Hexachlorobenzene[a,b,c]
Mirex[a]
Toxaphene[a]
Polychlorinated biphenyls (PCBs)[b,c]
Polychlorinated dibenzo-*p*-dioxins (Dioxins)[c]
Polychlorinated dibenzo-*p*-furans (Furans)[c]

NOTES: The United States has taken strong domestic action to reduce emissions of POPs. Currently, none of the pesticide POPs are registered for sale and distribution in the United States. In 1978, the US Congress prohibited the manufacture of any new PCBs and severely restricted the use of remaining stocks.

[a]Pesticides.
[b]Industrial Chemical.
[c]By-products.

SOURCES: UNEP Global Environmental Facility, 2003; IISD, 1998.

sources within the continental United States. Regulatory action has resulted in a 77 percent decline in total dioxin and furan releases between 1987 and 1995 (US EPA, 2005) (for more information see also US EPA 1987, 1991, 1994, 1995). Overall, levels of dioxins and DLCs in the environment have been declining for the past three decades. However, since dioxins are persistent compounds, they can be expected to remain in the environment and the food supply for many years to come (IOM, 2003).

Toxic Equivalency Factors (TEFs) are a convenient method for assessing the toxicity of mixtures containing dioxins and DLCs but there are uncertainties associated with calculating TEF values for individual congeners because of variability in their half-lives and differences in toxicity to humans. The reference compound for the TEF is the dioxin compound 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD). WHO recommends a tolerable daily intake of DLCs and PCBs of 1–4 pg/TEQ/kg/day (IOM, 2003). The US EPA has estimated 0.001 pg/kg/day of TCDD as the level associated with a 1 in 1 million excess risk for human health effects from exposure to DLCs and PCBs (IOM, 2003). The NRC committee on EPA's Exposure and

Human Health Reassessment of TCDD and Related Compounds (NRC, 2006) noted that the classification of DLCs as "carcinogenic to humans" vs. "likely to be carcinogenic to humans" is dependent on "the definition and interpretation of the specific criteria used for classification, with the explicit recognition that the true weight of evidence lies on a continuum with no bright line that easily distinguishes between these two categories."

Bioaccumulation of Dioxins in Seafood Exposure to dioxins and DLCs occurs when fish consume aquatic invertebrates that come in direct contact with dioxin particles that settle in sediment; through direct absorption through the gills; or by eating contaminated sediment, insects, and smaller fish (Evans, 1991). Because of their lipophilic character, dioxins and DLCs are distributed to fatty tissues in fish, including the liver and gonads. Muscle tissue is less contaminated, depending on the fat content of the muscle, which is likely to be greater in the older, larger, and oily fish.

Adverse Health Effects TCDD is used as the reference congener as a measure of toxicity for all dioxin-like compounds. Adverse health effects associated with exposure to dioxins have been identified in populations exposed through unintended industrial releases. One of the largest population exposures to TCDD occurred from an unintended industrial release in Seveso, Italy. Those who were exposed to the highest doses, primarily children, exhibited chloracne (Mocarelli et al., 1999), a severe skin disease with acne-like lesions that occur mainly on the face and upper body. Other adverse health outcomes included an increased risk for cancer. When compared to the nonexposed general population, the exposed population did not show an increased overall cancer mortality, but did have a significant excess mortality risk for esophageal cancer in males and bone cancer in females among those who were exposed to the lowest doses (Bertazzi et al., 1997). The US EPA (2000a) concluded that the cancer data on the Seveso population was difficult to interpret because of the small number of cases, exposure classification problems, and limited follow-up.

In 1997, the International Agency for Research on Cancer (IARC) placed TCDD in a Group I (agents with sufficient evidence of carcinogenicity for humans) designation, but weaknesses and inconsistencies among the positive studies published have made this designation controversial (Cole et al., 2003). The US EPA (2000a) considers TCDD to be a human carcinogen and other DLCs likely carcinogens, based on epidemiological and animal studies. Although epidemiological evidence alone does not support a causal relationship between dioxin exposure and cancer, US EPA (2000a) describes TCDD as a non-genotoxic carcinogen and a potent tumor promoter.

Polychlorinated Biphenyls

Polychlorinated biphenyls are also long-lived chlorinated aromatic compounds. They include over 200 chemical compounds in the form of oily fluids to heavier grease or waxy substances. Production of PCBs began in 1929, and the compounds were used as coolants and lubricants in transformers and other electrical equipment. Because of their noncombustible insulating characteristics, PCBs were used to reduce the flammability of materials used in schools, hospitals, factories, and office buildings. A variety of commercial products, including paints, plastics, newsprint, fluorescent light ballasts, and caulking materials contained PCBs until production was banned in the 1970s.

Local sources of PCBs may be more important than local sources of dioxins and DLCs for contamination of aquatic organisms. PCBs were legally widely discharged into rivers, streams, and open landfills between 1940 and the early 1970s. In 1976, the Toxic Substance Control Act (TSCA) was passed, calling for a ban on the manufacture, processing, distribution, and use of PCBs in all products in which the PCBs were not totally enclosed. The TSCA was based on three concerns: first, PCBs persist in the environment and resist biodegradation; second, a population-wide incident of human poisoning in Japan in 1968 was attributed to introduction of PCB-contaminated oil into a community; and third, in 1975 the CDC reported that, in rat experiments, oral gavage with Aroclor 1260 (a mixture of PCBs) caused liver cancer (Kimbrough et al., 1975). As a result of the TSCA, transformers and electrical capacitors that contained PCB compartments were sealed. Such transformers remain in place unless the seals leaked or were damaged, and by 1990, any PCB transformer within 30 meters of a commercial or public access building should have been replaced, registered, or provided with protection (US EPA, 1994).

Bioaccumulation of PCBs A significant correlation has been observed between blood PCB levels and the quantity of fish consumed by humans (Fein et al., 1984; Humpfrey, 1988; Jacobson et al., 1990; Smith and Gangolli, 2002). Bioaccumulation of dioxins and PCBs in the fatty tissues of food animals contributes to human body burdens through ingestion of animal fats in foods such as meat and full-fat dairy products. These foods are the largest contributors of dioxins and DLCs from the US food supply. The levels of dioxins, DLCs, and PCBs in seafood are generally greater than those in meat; however, actual exposure levels are far lower because of the lower consumption of fish among the general population (IOM, 2003). Fish oils that are used for supplements tend to have lower levels of dioxins, DLCs, and PCBs than fatty or oily fish as a result of processing methods

that remove these compounds from the final product (Source: http://www.ocean-nutrition.com/inside.asp?cmPageID=158).

Adverse Health Effects An extensive experimental literature on rodent and nonhuman primate models demonstrates that prenatal exposure to PCBs can interfere with neurodevelopment (Rice, 2000; Faroon et al., 2001; Bowers et al., 2004; Nguon et al., 2005). This literature is complemented by numerous prospective epidemiological studies of children conducted in Michigan; North Carolina; Oswego, NY; Germany; Faroe Islands; and the Netherlands (Schantz et al., 2003). The cohorts were often chosen to include children born to women who consumed fish from waters known to be contaminated with PCBs. The results of these epidemiological studies are generally congruent with those using animal models, although, as in most areas of observational research in humans, results are not always consistent across studies or consistent over time in a particular study.

Higher prenatal exposures have been associated with deficits in various functional domains including intelligence, attention, response inhibition, activity, and play behaviors (Jacobson and Jacobson, 1996; Patandin et al., 1999; Walkowiak et al., 2001; Vreugdenhil et al., 2002a,b; 2004; Jacobson and Jacobson, 2003; Stewart et al., 2003). However, there are some uncertainties about many key issues. One issue is the shape of the dose-effect relationship curve and, specifically, whether a threshold exists. A second is whether PCB exposure leading to adverse effects occurs prenatally or postnatally. Although most of the focus has been on prenatal exposures, some recent studies suggest that early postnatal exposures are also associated with neurotoxicities (Huisman et al., 1995; Walkowiak et al., 2001; Winneke et al., 2002). A third issue is the relative potency of the different congeners. For some neurodevelopmental outcomes, it is exposure to the dioxin-like congeners that is most strongly associated with deficits. A fourth issue is the impact of synergism between PCBs and other toxicants. Some studies suggest that adverse effects arise only when PCB exposure occurs in the presence of methylmercury or in environments in which individuals may be exposed to increased levels or multiple exposures (Grandjean et al., 2001; Roegge et al., 2004; Roegge and Schantz, 2006).

The PCB exposures identified in these study samples were considerably greater than those of the general US population. The median concentration of PCB 153 in the 10 studies, the only basis for direct comparison, ranged from 30 to 450 ng/g serum lipid, and the median of the 10 medians was 110 ng/g. The exposure levels in the two recent US studies were about one-third of those in the four earlier US studies or recent Dutch, German, and northern Québec studies (Longneker et al., 2003), consistent with exposure surveys indicating that PCB levels in human tissues in the United States have declined in recent decades (Sjodin et al., 2004a). In the most recent

Centers for Disease Control and Prevention (CDC) National Report of Human Exposure to Environmental Chemicals, the 95th percentile of the distribution of PCB 153 levels in the US population was 126 ng/g serum lipid (CDC, 2005d).

Animal studies carried out by CDC suggest that it is likely cancer risks were overstated and animal-specific. PCBs have been associated with health effects in laboratory animals, but typically at very high doses, possibly not relevant to noncatastrophic exposure for humans. Similar conclusions have been derived from looking at animal studies of exposure to high levels of PCBs resulting in tumor formation. Although there is evidence to substantiate PCB-associated health problems, several epidemiological studies of occupational workers exposed to PCBs found no evidence of ill health associated with their exposure. Even the PCB-chloracne association may be due to co-exposure to DLCs, and there is concern that multiple confounding factors make it difficult to interpret epidemiological studies in the workplace. Some studies of PCB workers found increases in rare liver cancers and malignant melanoma (US EPA, 2006). Thus, the US EPA found that the epidemiological studies are inconclusive; based on animal and recent human studies, PCBs are probable human carcinogens.

The earliest reported incidents of adverse effects from PCB poisoning occurred in Japan and Taiwan following widespread consumption of contaminated rice oil. The high-level exposure to PCBs resulted in skin lesions (acneform dermatitis) and peripheral nerve damage among adults, and similar effects among their offspring. Children born to exposed mothers also showed inhibition of growth and tissue maintenance (Kimbrough, 1987; Erickson, 1997). NRC (1999) also identified low birth weight and shorter gestation, and both neurological and neuromuscular deficits as adverse outcomes associated with prenatal PCB exposure.

Reports from occupational exposure to PCBs have identified several subclinical adverse health effects. The US EPA reviewed and identified many potentially serious noncancer adverse health effects associated with PCB exposure. These adverse effects included impairment of immune, reproductive, and neurological systems. The long-term impact of low-level exposure to PCBs is unclear, particularly on the endocrine system (US EPA, 2006) and will require further research to understand.

As PCB exposure levels continue to decline subsequent to federal laws banning PCB production, it may be difficult to characterize adverse health effects from low-level exposure (WHO Consultation on Risk Assessment of Non-Dioxin-Like PCBs, 2001; Ross, 2004) and to determine the significance of these exposure levels to health outcomes among the general population. Advances in analytic techniques may enhance data gathering and analysis efforts and improve our understanding of risks associated with low-level

TABLE 4-3 TEF Values from WHO (1998)

Compound	TEF value[a]
2,3,7,8-TCDD	1
Octachlorodibenzo-*p*-dioxins	0.0001
1,2,3,4,6,7,8,9-octachlorodibenzofuran	0.0001
3,3',4,4'-tetrachlorobiphenyl (PCB 77)	0.0001

[a]TEF = Toxicity Equivalency Factor, a numerical index that is used to compare the toxicity of different congeners and substances.

SOURCE: Van den Berg et al., 1998.

exposure as well as the role of specific PCB congeners or classes of congeners in health outcomes (Schantz et al., 2003; Ulbrick and Stahlmann, 2004).

Toxicity and Recommended Intake Limits for Dioxins, DLCs, and PCBs

Toxicity and Estimates of Risk The biological activity of dioxins, DLCs, and PCBs varies due to differences in toxicity and half-life of the various congeners. Variations in toxicity among congeners are related to a number of factors, including binding interaction at the cellular level with the arylhydrocarbon receptor (AhR) and variability in pharmacokinetics in vivo. Not all factors apply to all congeners; for example, many PCBs that do not have dioxin-like characteristics do not bind to the AhR. Van den Berg et al. (1998) describes factors used to determine the TEF values for dioxins, DLCs, and PCBs that include (but are not universal to all congeners):

- Structural relationships between congeners;
- Binding to the AhR;
- Toxic responses mediated through AhR activation; and
- Persistence and bioaccumulation.

The TEF value expresses the activity or toxicity of a specific congener relative to the toxicity of reference congeners, 2,3,7,8-TCDD; it is assigned a TEF of 1 and the toxicity of other congeners is expressed relative to TCDD (Van den Berg et al., 1998; IOM, 2003; SACN, 2004). Examples of some TEF values established by WHO are shown in Table 4-3. Toxicity can be additive in a mixture of congeners and so the Toxicity Equivalency (TEQ) of a mixture of DLCs is calculated by multiplying the concentration of each congener by its TEF, and summing across all DLCs in the mixture.

The Toxic Equivalency system is difficult to use, but it does permit extrapolation from 2,3,7,8-TCDD, a congener for which much is known.

WHO has recommended a Tolerable Daily Intake (TDI) of 1–4 pg/kg body weight per day for TCDD, and the TDI is applied to mixtures of dioxins and PCBs (IOM, 2003). Based on its estimate of cancer potency for DLCs, the US EPA concludes that intakes should not exceed 1–4 pg TEQ/kg/day in the general population (IOM, 2003).

DLC Exposure Limits in Foods With the exception of Canada and the United States, most countries utilize the TDI for assessing adverse health effects from exposure to DLCs and for setting acceptable limits in foods. The TDI represents an index for a contaminant similar to the adequate dietary intake (ADI) used for food additives. These limits are based on the assumption of an experimental threshold dose level below which no toxic effect is found in animal models, and include an additional uncertainty factor for extrapolation to humans.

The FDA and US EPA utilize probabilistic models to derive a Risk Specific Dose (RsD) for a contaminant. This model assumes the lowest dose that could result in a specific risk to humans, i.e., the dose with a lifetime cancer risk of 1 in 1 million. The use of the RfD, as previously described for methylmercury, was not applied to DLCs by the US EPA in its Draft Reassessment; the margins of exposure in the range of 100–1000 are generally considered inadequate to rule out the likelihood of significant effects occurring in humans, based on sensitive animal responses within the TEQ (US EPA, 1994; Foran et al., 2005a). Guidance on the development of risk-based meal consumption limits for 25 high-priority contaminants and analytes has been described by the US EPA (US EPA, 2000b). As described by the US EPA, a cancer slope factor (CSF) for carcinogenic risk can be calculated for DLC exposure of 1×10^{-3}/pg TEQ/kg/day (US EPA, 2000c). These risks are described later for analyzing benefits and risks associated with consuming farmed salmon (Foran et al., 2005b).

Exposure to DLCs from Seafood In 2002, the IOM Committee on the Implications of Dioxin in the Food Supply commissioned an exposure estimate for DLCs using intake estimates from the Continuing Survey of Food Intake by Individuals (CSFII) imputed to data from the FDA's Total Diet Study (Source: http://www.cfsan.fda.gov/~lrd/dioxdata.html). This analysis estimated that for all males and females in the general population, 1 year of age and older, the percentage contribution of fish and fish mixtures to the total DLC exposure from all foods was approximately 8 percent (IOM, 2003). When the data was analyzed for specific subgroups within the general population, the estimated contribution from fish and fish mixtures for pregnant and lactating women and for children (both males and females) aged 1 to 5 years was approximately 4 percent. By comparison, the estimated

contribution of meat and meat mixtures to the total DLC exposure for these groups was approximately 37 and 35 percent, respectively, for pregnant and lactating women compared to children aged 1–5 years (IOM, 2003).

Polybrominated Diphenyl Ethers

Polybrominated diphenyl ethers (PBDEs) are synthetic compounds that are added to a variety of materials to increase their fire resistance. PBDEs are structurally similar to PCBs, and can exist, theoretically, as 209 distinct isomers. PBDEs are released into the environment as emissions from facilities manufacturing them and as a result of degradation, recycling, or disposal of products that contain them. The patterns of use of PBDEs are changing rapidly.

Bioaccumulation of PBDEs As with other persistent organic pollutants, PBDEs are cycled globally (de Wit et al., 2004). PBDE levels in aquatic wildlife have increased rapidly in recent decades (Ikonomou et al., 2002; Law et al., 2003), with doubling times of between 1.6 years and 6.0 years (Lunder and Sharp, 2003; Rayne et al., 2003; Hites et al., 2004a). PBDE tissue (blood, milk, and adipose) levels in humans have followed a time course similar to that in wildlife. The concentrations in human milk samples in Sweden, British Columbia, and the United States have increased manyfold over recent decades (Darneud et al., 2001; Ryan et al., 2002; Hites, 2004; Sjodin et al., 2004a; Schecter et al., 2005), with doubling times of 10 years or less (Meironyte et al., 1999; Ryan et al., 2002). For reasons that are not known, the concentrations of PBDEs in biological tissues collected in North America are at least 10 times greater than those collected in Europe or Japan (Peele, 2004). Although ingestion is considered to be an important route of exposure to PBDEs, the importance of other routes, such as indoor air and dust, are poorly characterized and could be important in certain settings (Sjodin et al., 2004b).

Although the concentrations of PBDEs have been found to vary widely across countries, market basket surveys, total diet studies, duplicate diet studies, and commodity-specific surveys have repeatedly shown that, within a region, fish and shellfish tend to have PBDE concentrations that are greater than those found in dairy products, eggs, fats, and oils, and other meat products are important sources of exposure to PBDEs. This has been found in Canada, Finland, Germany, Japan, the Netherlands, Sweden, and the United States. In terms of total intake of PBDEs, fish and shellfish are the major contributors in Europe and Japan, while meats and poultry are the major contributors in the United States and Canada (FAO/WHO JECFA, 2005). The PBDE concentration tends to be greater in fish at higher trophic levels, i.e., predatory fish (Rice, 2005). In a market basket survey

conducted in Dallas, Texas (Schecter et al., 2004), the highest levels of total PBDEs were found in samples of salmon, catfish, and shark. It is notable that the congener pattern was highly variable across samples, even within types (e.g., catfish), perhaps reflecting site specificity in the magnitude and nature of the problem of PBDE contamination. Total PBDE levels were also greater in meats with relatively high fat content, such as pork sausage, hot dogs, and duck; and in dairy products with higher fat content, such as cheese and butter (Schecter et al., 2004). Similar findings were reported in a market basket survey of foods conducted in California (Luksemburg et al., 2004), in which the highest PBDE levels were found in swordfish, Alaskan halibut, and Atlantic salmon. PBDE levels were 15 times greater in Pacific farm-raised salmon than in Pacific wild salmon (Easton et al., 2002). PBDE levels are higher in salmon farmed in the United States and Europe than in Chile (Hites et al., 2004a). Limited data are available, however, on the association between seafood consumption and PBDE levels in human tissues. In a small study of 94 urban anglers in the New York–New Jersey area, greater consumption of locally caught fish was not significantly related to blood PBDE levels, suggesting that, at least at this time and in this study population, consumption of local fish is not a major route of exposure to PBDEs (Moreland et al., 2005).

Adverse Health Effects The data available on the toxicity of PBDEs are extremely limited. Experimental animal studies indicate that PBDEs affect the nervous (Viberg et al., 2003), endocrine (Stocker et al., 2004), and immune systems (Fowles et al., 1994), and that the potency of PBDEs might be comparable to that of PCBs, although considerable uncertainty remains (Kodavanti and Ward, 2005). No population-based epidemiological studies have evaluated the human health effects of environmental exposure to PBDEs. It is not known whether all PBDEs share a common mechanism of action, complicating any effort to characterize toxicity using a toxic equivalence factor approach. In light of the fact that in vitro studies with purified PBDE congeners do not show AhR activation, it is possible that the presence of trace amounts of DLCs have confounded these assessments of PBDE toxicity (FAO/WHO JECFA, 2006). The FAO/WHO Joint Expert Committee on Food Additives and Contaminants concluded that the toxicological data available on PBDEs were insufficient to establish a Provisional Tolerable Weekly Intake (FAO/WHO JECFA, 2005). The data, however, are not sufficient to identify "no observed adverse effect levels" (NOAELs) for congeners of greatest interest, and thus to draw inferences about the prevalence of exposures of concern in the US population.

Levels of POPs in Seafood

Because of their lipophilic character, persistent organic pollutants are absorbed and transported to fatty tissues in fish and marine mammals. Uptake of POPs can occur through exposure from sediments in water or via consumption of smaller fish by predatory species (Geyer et al., 2000).

Farmed fish are exposed to these contaminants to the extent that they are present in feed (Hites et al., 2004a). Recently, Hites et al. (2004a) found that, perhaps because of their higher fat levels, some farmed salmon contain significantly higher concentrations of certain organochlorine contaminants, including PCBs, than wild-caught salmon. In addition, PCB concentrations in samples of commercial salmon feed purchased in Europe were higher than those in samples purchased in North and South America, suggesting that regional differences in the composition of feed contribute to regional differences in the PCB concentrations in farmed salmon. The mean wet weight concentration of PCBs in farmed salmon was 50 ng/g or below (Hites et al., 2004a), regardless of source, and thus below the Food and Drug Administration (FDA) action level of 2 ppm for PCBs in food. Using the US EPA risk assessment for PCB and cancer risk, Hites et al. (2004a) concluded that, given the PCB levels in the fish samples, a consumer's risk will not be increased if consumption is limited to no more than 1 meal per month of farmed salmon. Given the substantial regional differences found in PCB levels, however, these analyses demonstrated the importance for the consumer of knowing whether a fish was farmed or wild-caught and also its region of origin.

In a subsequent paper, the same group of investigators reported a quantitative analysis of competing risks and benefits associated with consuming farmed Atlantic and wild-caught Pacific salmon, for both cancer and noncancer end points (Foran et al., 2005b). Sixteen organic contaminants were considered. A benefit/cancer risk ratio was calculated for cancer using cancer slope factors developed by the US EPA (assuming that a $1 \cdot 10^{-5}$ risk is acceptable) and a benefit/noncancer risk ratio using reference doses established by the US EPA. Foran et al. (2005b) concluded that neither farmed nor wild-caught salmon can be consumed in quantities that would provide 1 g/day of EPA/DHA while still maintaining an acceptable level of carcinogenic risk ($1 \cdot 10^{-5}$). In contrast, they determined that based on the benefit/noncarcinogenic risk ratio, wild-caught salmon could be consumed in amounts consistent with EPA/DHA intake levels recommended by the American Heart Association (see Chapter 2).

As expected, however, the results differed for farmed and wild-caught salmon. Consuming farmed salmon in amounts that provides 1 g/day of EPA/DHA would produce a cumulative cancer risk that is 24 times the acceptable cancer risk level. For wild-caught salmon, the cumulative cancer risk would be eight times the acceptable level. Both farmed and wild-caught

salmon could be consumed in amounts that provide at least 1 g/day of EPA/DHA per unit of noncarcinogenic risk (Foran et al., 2005b).

These analyses were conducted assuming salmon intake needed to provide 1 g/day of EPA/DHA. The authors interpreted the WHO intake recommendation for omega-3 fatty acids as corresponding to 2–3 g/day; this includes alpha-linolenic acid (ALA) intake, which is derived primarily from plant sources such as soy, flaxseed, and walnut oils (see Chapter 1). The analysis of Foran et al. (2005b) was based on the assumption that the 2–3 g/day of omega-3 fatty acids applied only to EPA/DHA and did not take ALA into consideration. The WHO (2003) recommendation for fish consumption is 1–2 servings per week; it assumes that this level of consumption would provide 200–500 mg of EPA/DHA, considerably less than the intake of 1 g/day EPA/DHA from fish that Foran et al. assumed. These analyses represent a "worst case" scenario in that it is assumed that consumption of salmon would be the sole source of omega-3 fatty acids. Further, it assumed that salmon would provide all omega-3 fatty acids (DHA, EPA, and ALA) and salmon is not a source of ALA. Their analysis was based on data obtained prior to the implementation of industry safety measures for the prevention of POP contamination of aquaculture products (Santerre, 2004). It is worth emphasizing that because the food supply is dynamic, benefit-risk analyses are not static (Willett, 2006).

Body Burdens of POPs

Body burden can be defined as the total amount of a chemical in the human body or in human tissue from exposure to contaminants found in the environment (DeCaprio, 1997; Mendelsohn et al., 1998; IOM, 2003). CDC monitors over 200 contaminants with the aim of identifying baseline concentrations of specific substances and determining trends in body burdens among the general population (http://www.cdc.gov/biomonitoring/overview.htm; Kamrin, 2004). CDC reports (CDC, 2004; 2005b) include data on human exposure to approximately 150 compounds, including potential seafood contaminants such as lead, mercury, and many POPs. Technological advancements now afford the ability to detect minute levels of contaminants in human tissue, although detection of such contaminants does not indicate that a hazard or risk is present. For example, individuals regularly consuming fish from the Great Lakes were reported to have higher serum dichlorodiphenyl dichloroethene (DDE) concentrations (median 10 µg/L) compared to those who did not eat fish (1 µg/L); however, they did not show impaired motor function, impaired visuospatial function, or reduced memory and learning (Schantz et al., 1999; 2001; Rogan and Chen, 2005).

Body burdens for PCBs have been reviewed in studies of fish-consuming populations by the US EPA (US EPA, 2000a,c). The review did not show any

cases among the general population of PCB exposure through fish consumption that exceeded the upper limit of background exposure, although it did find that consumers who had higher consumption levels of fish with typical PCDD/PCDF profiles than the general population may receive up to five times the mean intake exposure level of the general population (Armstrong, 2002). To illustrate, sport fishers living near an industrial release site in the United States had blood PCB levels (both dioxin-like and nondioxin-like congeners) three times higher than control groups eating fish from areas that were not highly contaminated (US EPA, 2000c).

Toxicological and epidemiological data suggests that the population does not necessarily incur adverse health effects from the majority of chemicals currently detected in biomonitoring programs (US EPA, 2005). Thus, biomonitoring measures the level of the contaminant in a biological sample, which is not used to correlate such data to toxicology studies in animals; rather, biomonitoring gives a picture of a person's body burden at one particular point in time, and it can be difficult to determine when the exposure might have occurred (Paustenbach and Galbraith, 2005). Biomonitoring measurements are relevant exposure assessment tools because they indicate body burden levels from all environmental sources (e.g., air, soil, water, dust, food) combined. The purpose of the CDC national biomonitoring programs is to determine which environmental chemicals are absorbed, measure exposure levels, assess health impacts of exposure on population groups (e.g., pregnant women and children), determine exposure risks among population groups, and monitor trends over time (Source: http://www.cdc.gov/biomonitoring/overview.htm). Research investigations may be utilized to identify specific sources of the elevated exposure and action to deal with the sources (Paustenbach and Galbraith, 2005).

Summary of Evidence

Evidence for specific adverse health effects associated with exposure to POPs is inconsistent. Among confounding factors related to this class of contaminant is the uncertainty that accompanies association of specific disease outcomes with low-level exposures. An issue of particular concern is the inability to determine a threshold for an adverse effect. Thus, the determination of toxicity related to exposure to POPs is challenging and requires further research.

INTERACTIONS BETWEEN NUTRIENTS AND CONTAMINANTS IN SEAFOOD

Selenium and Seafood Contaminants

There are several distinct ways that selenium may influence the impact of toxicants, e.g., through hepatic and extrahepatic detoxification mecha - nisms, effects on oxidative stress, modulating the immune response, and some novel sequestering mechanism rendering toxicants, e.g., heavy metals, inactive.

As noted previously, mercury, i.e., elemental mercury (Hg), ionic mer - cury (Hg^{+}), and organic mercury (MeHg), may exist in three different states, and each state likely governs how selenium may interact with this element. MeHg has been implicated as a neurotoxicant, a mutagen, and a teratogen in various organisms. Epidemiological studies have been conducted on the exposure of humans to mercury through consumption of fish and marine mammals in different geographical areas including Seychelles, the Canadian North, the Amazon, Faroe Islands, Papua New Guinea, and Sweden. There are inconsistencies among these studies in the toxic dose, which may be due to differences in dietary patterns between the populations studied, e.g., more whale meat is consumed in Faroe Islands and more fish in Seychelles (Chapman and Chan, 2000) (see Box 4-1). Additionally, toxicity assess - ments were not conducted in all of the study locations and where they were the results may not be comparable in terms of populations examined and outcomes assessed.

Coexposure to selenium may diminish the toxic effects of some forms of mercury and other heavy metals, including cadmium and silver (Whanger, 1985). The mechanisms for these interactions are only partially understood but their occurrence certainly influences the determination of safe and toxic levels of such metals for persons in the general population. Selenium was first reported to counteract acute mercuric chloride toxicity by Parizek and Ostadalova (1967). Later, Ganther et al. (1972) showed the mitigating effect of sodium selenite on the toxicity of methylmercury. When selenite and mercuric chloride are co-adminstered, these elements react in the bloodstream forming complexes at an equimolar ratio. This reaction may explain the consistent equimolar ratio of selenium and mercury in tissues of seals and other marine mammals (Koeman et al., 1973; 1975) and mer - cury mine workers (Kosta et al., 1975). In nearly all marine fish sampled, the stoichiometric mercury-to-selenium ratio was less than 1. In contrast, freshwater fish accumulate mercury in such a way that the stoichiometric ratio was greater than 1 (Luten et al., 1980; Whanger, 1985; Cuvin-Aralar and Furness, 1991; Ikemoto et al., 2004). Despite extremely high values for mercury and selenium, sea fish are protected against toxicity of either element. It is interesting to note that adding selenium to lakes contami -

nated with mercury has been shown to be an effective remediation process (Paulsson and Lundbergh, 1989).

Selenide has one of the highest known mercury binding constants and will avidly partner with mercury (Whanger, 1985). Therefore, if dietary or tissue selenium is limited, selenide will be bound by mercury resulting in a lack of selenocysteine for incorporation into vital selenoproteins. The sequestered complex of mercury-selenium is highly insoluble and can be localized in lysosomes. Such sequestered material seems to be an inconsequential accumulation, with no toxicity to the animal.

It should be noted that ocean fish, though not lake fish, are a rich source of selenium. The US Department of Agriculture (USDA) ranked fish sources as 16 of the top 25 (out of a total of 1100) selenium-containing foods (USDA, Release 18. It has been suggested that the differences in mercury toxicity found in the Faroe Islands study compared to the Seychelles study may be due to the fact that mothers in the Faroe Islands ate whale meat, which is low in selenium, while mothers in the Seychelles studies ate seafood, which is rich in selenium (Ralston, 2005). This hypothesis is likely too simplistic, however, given that the Faroese also consume large amounts of seafood other than pilot whale.

Overall, selenium in the form of selenide is pivotal with regards to forming key selenoproteins and interacting with various heavy metals, such as mercury, to form a sequestered inert complex of mercury and selenocompounds, i.e., bis(methylmercuric)selenide (BMS) (Yoneda and Suzuki, 1997; Watanabe, 2002). MeHg might be acting as a methyl donor, thereby sparing the amount of S-adenosylmethionine (SAM) required for methylation. The net effect would be demethylation of MeHg by selenide, which then could lead to other interactions between selenide molecules and newly formed ionic Hg (Gregus et al., 2001; Watanabe 2002). Evidence suggests that the two elements interact with protein through basic amino acids in the molecule and also that the protein may be one of the heparin-binding proteins (Yoneda and Suzuki, 1997).

RISKS ASSOCIATED WITH MORE ACUTE SEAFOODBORNE HAZARDS

Microbiological Hazards

The best measures of seafood safety in the United States are based on illness reports compiled by the CDC (Source: http://cdc.gov/foodnet/) and the respective epidemiology programs in each state. Complementary lists of seafoodborne illness were also compiled by the Center for Science in the Public Interest (CSPI) (DeWaal and Barlow, 2004). Although these data are compromised by limited reporting and a large portion of unidentified etio-

logical agents or nonspecific food vehicles, they remain the best measures of causes and trends in seafoodborne illnesses.

CDC estimates during the years prior to 1980 with less informative reporting suggested approximately 11 percent of all foodborne outbreaks (an outbreak involves two or more cases from a common source) implicated fish, mollusks, or crustaceans as the food vehicle (Bryan, 1980). Compilations of CDC data from 1978–1987 indicated fish and shellfish constituted only 10.5 percent of foodborne outbreaks and 3.6 percent of total cases (IOM, 1991). Estimates from the same data indicated "both [the percentage of] people made ill from beef (4) and turkey (3.7) exceeded total illnesses from seafood (3.5), whereas pork (2.7) and chicken (2.6) were each slightly lower. When shellfish (2.3 percent) and fish (1.2 percent) were considered separately, the number of reported cases from each was lower than for any other animal meat category" (IOM, 1991). These comparisons did not adjust for per capita consumption. FAO's compilation of CDC's data indicated that the number of cases remained higher for shellfish, but that outbreaks for fish, of which 90 percent could be linked to the cause, are more common (Huss et al., 2004). The association between exposure and illness is considered higher for seafood than for other foods due to the early onset of symptoms and the particular symptoms per types of seafood. This situation reinforces reporting of seafoodborne illnesses. Table 4-4 summarizes commonly encountered hazards and risks associated with classes of seafood consumed in the United States, and systems in place to control or minimize potential exposure risks.

Estimating Frequency of Seafoodborne Illnesses

CDC estimates for foodborne illnesses (76 million/year) and related deaths (5000/year) (Mead et al., 1999) indicated that the number of cases were reduced by 6.2 and 44.4 percent, respectively, from previous estimates from Archer and Kvenberg (1985), which were based on foodborne diarrheal diseases alone. These reports did not include any specific references to seafood other than data involving various food-related *Vibrio* infections. Although *Vibrio*-related illnesses are not a CDC-reportable disease and therefore may be underreported, Mead et al. (1999) included cases and outbreaks involving *Vibrios*, which frequently implicate seafood, particularly raw molluscan shellfish, as a likely vehicle. This study accounted for underreporting of foodborne illnesses through the use of multipliers (see Table 4-5). The less serious an illness experienced by an individual, the less likely they are to seek medical attention and thus minor illnesses are less likely to be reported. A low multiplier is needed to accurately depict the actual number of cases of a serious illness, such as those associated with *Vibrio vulnificus*.

Huss et al. (2004) compiled data from CSPI indicating consumption of molluscan shellfish caused the highest percentage of seafoodborne cases (individual illnesses) during 1990–1998, but the primary causative agent was reported in the collective category for noroviruses (see Table 4-6). The general norovirus category accounted for the large majority of seafoodborne outbreaks reported by CSPI (DeWaal and Barlow, 2004) from their survey of reported illness during 1990–2003. The most recent CDC report (2005a) suggested the incidence of infections involving *Vibrio* bacteria has been increasing (Figure 4-4), using the estimated number of total incidences based on laboratory-confirmed infections divided by the population estimates. The extent of the estimated affected population was equated to 15.2 percent of the US population. This report did not distinguish the *Vibrio* species or food vehicles involved, but it did suggest some of the *Vibrio* infections may have resulted from nonfoodborne sources, e.g., previous wounds.

With the exception of concerns for *Vibrio* and Norovirus infections, in general, the CDC report (2005a) does not reflect an increase in seafood-borne illnesses, particularly of microbial origin (most commonly associated with consumption of raw molluscan shellfish). Figures reported by CDC (2005a) are imprecise due to inclusion of other nonfoodborne causes and changes in state reporting. Since 1988, CDC has maintained only a voluntary *Vibrio* surveillance system for culture-confirmed infections in the states contiguous to the Gulf of Mexico. In 1999, the Foodborne and Diarrheal Disease Branch of CDC encouraged all state epidemiology programs to improve *Vibrio* reporting and the Council for State and Territorial Epidemiologists has drafted a resolution calling for more mandatory reporting of *Vibrio*-related illnesses (Personal communication, K. Moore, Interstate Shellfish Sanitation Conference, November, 2005).

Reducing Risk of Seafoodborne Illness

***Vibrio*-Associated Illness** The *Vibrio* family of bacteria are indigenous to most coastal environments; the particular types and amounts present are influenced by salinity and water temperature (IOM, 1991). Filter-feeding animals, e.g., oysters, will take up chemical and microbial flora, including *Vibrios*, in their immediate environment. The two species of concern are *Vibrio vulnificus* (*Vv*) and *Vibrio parahaemolyticus* (*Vp*). Like the related *Vibrio* cholera species, *Vv* and *Vp* can live in warm seawater and have been isolated from oysters, clams, crabs, and finfish. In contrast, *Vv* can cause serious illness (wound infections, gastroenteritis, or a syndrome known as "primary septicemia") and death in persons with pre-existing liver disease or compromised immune systems while *Vp* typically causes less severe illness. *Vp* can infect healthy consumers yet severe disease is rare.

TABLE 4-4 Current Seafood Safety Hazards, Controls, and Risks

Hazardous Seafood[a]	Hazard[b]	Severity to Consumers	Occurrence and Trend
Raw bivalve mollusks (oysters, clams, mussels)	(1) Viruses, enteric bacteria (2) *Vibrio ↑ulnificus* (3) *Vibrio parahaemolyticus*	(1 & 3) Mostly mild gastroenteritis; certain types and serotypes can be more harmful for very few consumers (2) Severe for "at-risk" consumers[c]	(1) Random by location and time; improper water classification; recreational harvests (2) Rare yet persistent; primarily warm-water products involving at-risk consumers (3) Sporadic; may be increasing
Natural toxins Finfish (1 & 2) Mollusk (3)	(1) Ciguatera (2) Scombroid poisoning (3) PSP, NSP, DSP, ASP	(1) Moderate to severe and reported prolonged symptoms in some cases (2) Mild and short duration (3) Mild to severe relative to toxin type	(1) Limited to certain fish species from certain areas; could increase with more imports (2) Limited but persistent for certain species subject to thermal abuse; could increase with more imports (3) Rare but can be very serious; could increase with global warming and related environmental changes
Processed seafood	(1) *Salmonella* (2) *Listeria monocytogenes* (3) *C. perfringens* (4) *C. botulinum* (5) *Shigella* (6) *Staphylococcus aureus* (7) HAV and NLV	Usually mild; can be severe to very severe for (2) and (4), respectively, yet occurrence very rare	Very limited and decreasing; more prevalent in ready-to-eat items; could increase with more and certain imports
Allergies	Host specific	Host specific; can be mild to severe	Seafood ranked in top four food allergies; could increase for pre-formulated, value-added products

NOTE: PSP = paralytic shellfish poisoning; NSP = neurotoxic poisoning; DSP = diarrhetic shellfish poisoning; ASP = amnesic shellfish poisoning; HAV = hepatitis A virus; NLV = Norwalk-like viruses (Noroviruses) spp.

[a]Fish or shellfish, the consumption of which can lead to disease. Ranked in order of concern per occurrence and risk.

Risk to Consumers	Facts Enhancing Risk	Factors Reducing Risk
High for consumers' preferred raw mollusks; particular concern for at-risk consumers	(1) Unapproved waters, improper harvest water classifications; recreational harvest disregards advice (2) Natural occurrence and host factors (3) Post-harvest temperature abuse	(1) Approved waters; revised indicator programs (2 & 3); cooking; rapid and continued cooling; Post Harvest Processing (PHP) methods to reduce number of organisms; thermal mapping of harvest areas; consumer education
(1) Higher in endemic areas for certain fish species; recreational harvest and illegal sales (2) High for consumption of few species; more common for certain imported species (3) High if harvest is uncontrolled or recreational interest disregards advice	(1) Commercial and recreational harvest from specific areas for certain fish, i.e., reef species; no recognized screening methods; problematic species identified (2) Temperature abuse after capture of certain fish species; no practical screening methods (3) Lack of harvest controls; recreational shellfish harvest	(1) Restrict harvest and consumption of certain fish from certain areas; designate approved fish and harvest areas; restrict recreational sales (2) Temperature controls and monitoring for histamines; harvester education; screening for imports and suspect fish (3) Regional water and product monitoring programs; consumer education
Low when adequate cooking precedes consumption	Cross-contamination; temperature abuse; processing errors; mishandling by retail sections, restaurants, and consumers	Adequate cooking; temperature controls; proper processing and food service; proper satisfaction; consumer education; use of polymerase chain reaction-based detection for viruses
Moderate without proper labeling and product identification	Formulated products with seafood ingredients; mislabeling; cross-cooking	Proper seafood identification; cleaning and sanitizing of equipment to avoid cross-contamination

[b]An organism, substance, or condition having the potential to cause disease.

[c]At-risk consumers include consumers with pre-existing health conditions, e.g., immuno - compromised, that place the consumer in a predisposed category for seafoodborne illnesses.

SOURCE: Revised from IOM, 1991.

TABLE 4-5 Multipliers Used by CDC to Estimate Total Cases for Different Foodborne Bacterial Illnesses Based on Actual Reported Cases

Agent Causing Illness	Multiplier for Estimated Cases
Campylobacteria *Clostridium perfringens* *Salmonella*, nontyphoidal *Staphylococcus aureus*	38
E. coli O157:H7 *Shigella* *Vibrio*, other spp.	20
Bacillus cereus	10
Clostridium botulinum *Salmonella typhi* *Vibrio cholerae*, toxigenic *Vibrio vulnificus*	2

SOURCES: Derived from Mead et al., 1999; 2006.

TABLE 4-6 Seafoodborne Diseases Traced to "Molluscan Shellfish" in the United States from 1990 to 1998, and Outbreaks and Cases for Which the Etiological Agent Has Been Identified

	Outbreaks		Cases	
Agent	Total	Percent	Total	Percent
V. parahaemolytics	18	27	733	22
Noro-/Norwalk-like virus[a]	15	23	2175	66
PSP/toxin	14	20	92	3
Salmonella	6	9	183	6
Scombroid	2	3	4	—
Ciguatera	3	5	5	—
Shigella	2	3	17	0.5
Campylobacter	2	3	6	—
V. vulnificus	1	—	2	—
V. alginolyticus	1	—	4	—
C. perfringens	1	—	57	2
Giardia	1	—	3	—
Total	66	93	3281	100

[a]Norovirus was recently approved as the official genus name for the group of viruses provisionally described as "Norwalk-like viruses" (NLV) (http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus.htm).

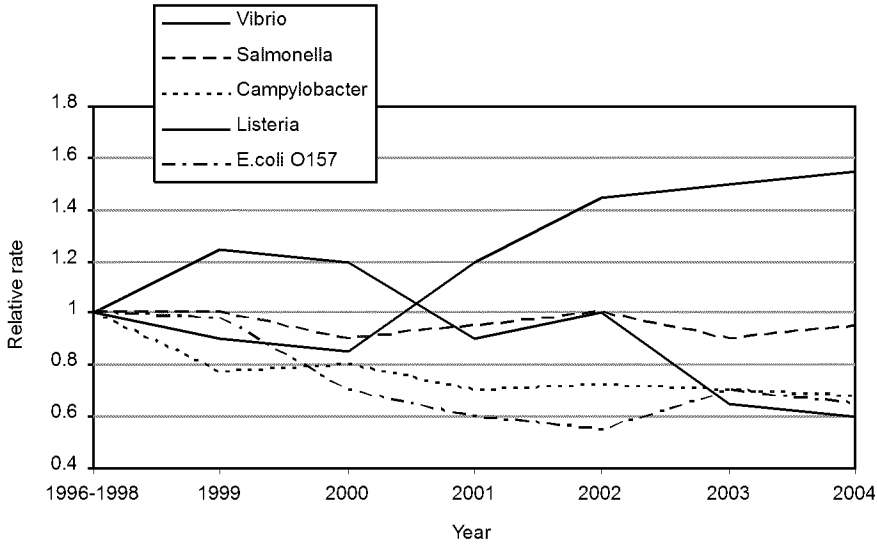

FIGURE 4-4 Relative rates (compared with 1996) of laboratory-confirmed cases of *Yersinia*, *Escherichia coli* O157, *Campylobacter*, and *Salmonella*, by year; from Foodborne Diseases Active Surveillance Network, United States, 1996–2004. SOURCE: CDC, 2005a.

More detailed assessment of the *Vibrio* illnesses from seafood can be found in state reports for *Vibrio ↑ulnificus* (see Table 4-7). These reports provide more specific data for infections resulting from consumption of raw molluscan shellfish of commercial origin. With the exception of California, the majority of reported illnesses involve the oyster-producing regions about the Gulf of Mexico, due to the relative prevalence of *V↑* in warmer coastal waters. The number of *V↑* illnesses involving commercial shellfish harvests per year across all states reporting (32) during 1995–2004 averages less than one case per year (0.98 cases/year/state). The justification for the persistent concern about *V↑* stems from the potentially severe consequences for consumers in a higher risk category for infection (e.g., immunocompromised) for whom there may be as much as a 50 percent mortality rate (IOM, 1991; Hlady and Klontz, 1996).

California, Florida, Louisiana, and Texas represent "core states" designated in a *V↑* management plan designed by FDA through cooperation with the Interstate Shellfish Sanitation Conference (ISSC, 2002) to reduce *V↑* illnesses from raw oyster consumption (see Table 4-8). This plan was

TABLE 4-7 Individual Reported *Vibrio ↑ulnificus* Cases of Illness Involving Commercial Oyster Products

State	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	Avg/Yr
CA	5	7	2	2	8	7	7	6	1		4.5
FL	8	5	6	14	12	5	11	5	12	8	8.6
LA	2	2	1	7	2	1	4	1	1	2	2.3
TX	1	8	7	2	6	9	7	5	6	3	5.4
AL	4	2	1	3		1	1		2	2	1.6
AR	1	1	1			1	1				0.5
AZ	1			2			1	1			0.5
CO										2	0.2
CT						1					0.1
GA	2	3		4	1	1	6	5	5	3	3.0
IL					1		1				0.2
IN									1		0.1
KY				1	1						0.2
MD								2		2	0.4
ME								1			0.1
MI					1					1	0.2
MO	1					1		1			0.2
MS			1	1							0.2
NC			1	2	1	1		1		1	0.7
NJ										1	0.1
NM									1	1	0.2
NV				1	1						0.2
NY		1								1	0.2
OH						1				2	0.3
OK				1				1		1	0.3
OR								1			0.1
PA					1						0.1
SC		4						3		2	0.9
TN	1							1	2		0.4
VA			1		1			1	2		0.5
VI				1		1					0.2
WI							1				0.1
Totals	26	33	21	41	36	30	40	35	33	32	
Avg/state/year											0.98

NOTE: A blank cell means no reported cases.
SOURCE: Personal communication, A.P. Rainosek, National Oceanographic and Atmospheric Administration Fisheries, National Seafood Inspection Laboratory, Pascagoula, MS, July 2005 (Data prepared for the Interstate Shellfish Sanitation Conference).

complemented with a formal risk assessment conducted for*V↑* (FAO/WHO, 2001). The plan includes specified industry performance goals for illness reduction rates and consequences if the goals are not attained.

Commercial operations have responded with post-harvest processing procedures such as high-pressure, low-temperature pasteurization and

TABLE 4-8 Abbreviated Table of Compliance for Core States as Specified in the ISSC's *Vibrio vulnificus* Management Plan

Deadline	Post-Harvest Treatments[a]	Illness Reductions[b]	Florida Example[c]
December 2004	25% capacity		9/year—baseline
2005–2006		40% (average)	5/year—goal
December 2006	50% capacity		
2007–2008		60% (average)	4/year—goal
	If the 60 percent illness reduction rate is not collectively achieved by 2008, additional controls can be imposed, including harvest restrictions or closures relative to water temperatures and special labels designating product to be shucked by a certified oyster dealer.		

NOTE: Core states are California, Florida, Louisiana, and Texas.

[a]Post-harvest treatment "capacity will be based on all oysters intended for raw, half-shelled market during the months of May through September harvested from source states, to include the capacity of all operational plants and the capacity of plants under construction."

[b]Illness reductions will be based on the average illness rate for years 1995–1999 of 0.036/million persons, using data from California, Florida, Louisiana, and Texas. Adjustments in methodology can be adopted based on further review.

[c]The Florida example indicates the performance goals (total reported illnesses per year) that must be attained for compliance relative to the initial established baseline.

SOURCES: ISSC, 2001, 2002, 2003b.

"frosting" methods to kill *V.* in the oysters as part of the illness reduction efforts. FDA (2005a) has recently approved the use of irradiation as another post-harvest processing option.

This risk management plan also includes recommendations for a public education component including programs targeting consumers of raw oysters, both those with and those without health conditions that increase their risk of *V.* infection. In the states that were required to develop risk-management plans, Flattery and Bashin (2003) conducted a survey to elicit new information about media exposure, attitudes, and consumption behavior from consumers of raw oysters. They found that (1) generally, consumer awareness of who should avoid consuming raw oysters is limited; (2) many at-risk consumers are already taking some actions, albeit ineffective, to avoid illness; (3) one in three consumers are eating raw oysters less frequently. International Conference on Emerging Infections and Diseases (2006) also reported a decline in "risky food consumption." This survey response showed a decline of one-third in the number of individuals who reported consuming foods, including raw oysters, associated with a higher risk for foodborne disease.

Flattery and Bashin (2003) determined that to increase the effectiveness of the educational component of the plan, key messages should identify at-

risk consumers; communicate effective action to prevent illness (i.e., refrain from eating raw oysters); and address popular myths about preventing illness.

It may be difficult to determine precisely the reduction in illnesses achieved because of the large standard deviation about the annual mean (the average illness rate for 1995–1999 of 0.036/million persons, based on data from California, Florida, Louisiana, and Texas) reported by ISSC (2001, 2002). At present, the number of *Vibrio* illnesses reported annually is small. For example, in Florida the 40 and 60 percent illness reduction goals represent a drop in reported illnesses from nine/year to five/year by 2006, and to four/year by 2008 (see Table 4-8 and Table 4-9). The recent increase in reporting from states that had not previously monitored *Vibrio* illnesses shows that national trends for reported illnesses are similar to those for the core states.

Management plans are also being considered to address illnesses due to *Vibrio parahaemolyticus (Vp)* from raw shellfish. Illnesses resulting from this source are less severe than for *V.v*, but occurrence is not confined to at-risk consumers. Further, international occurrence of certain *Vp* strains suggests the possibility of a pandemic infection because these strains have been identified as deriving from a known pathogenic strain of *Vp* (Chowdjury et al., 2000). *Vp* is a leading cause of seafoodborne illnesses in Japan and eastern Asian countries noted for higher consumption of raw seafood.

Infections in the United States are more sporadic and have involved crabs, shrimp, and crayfish, with cross-contamination of raw and previously cooked product as a contributing factor, although raw oysters remain the primary vehicle for *Vp* infections. *Vp* elicited little response from the National Shellfish Sanitation Program (NSSP) prior to two major outbreaks in the Gulf Coast region in 1997 and 1998, some cases of which involved a previously unreported and more virulent serotype (03:K6) from Asia (FDA, 1999). Recent outbreaks of *Vp* have also occurred in the more temperate waters of the northwest United States and Canada (Fyfe et al., 1998; CDC, 2006a,b). Infection prevention is complicated by the ability of *Vp* to grow in the oysters after harvest, particularly in the absence of adequate temperature control. Preventive measures for *Vp* are similar to those for *V.v* and include cooking, post-harvest temperature controls, and consumer and processor education and processing innovations. In the absence of regulatory mandates the FDA offers voluntary guidance indicating that no more than 10,000 bacteria per gram of raw shellfish (FDA, 2001b) should be present.

Other Bacterial Hazards

In addition to *Vibrios*, a variety of potentially pathogenic bacteria have been associated with seafood safety risks, though actual occurrence is very

TABLE 4-9 Human Pathogens Associated with Seafood

Pathogens	Isolated from Seafoods	Proven Pathogen in Seafood	Pathogen Source[a]
Organisms That Can Cause Disease in Normal, Healthy Adults			
Bacteria			
Vibrio cholerae O1	Yes	Yes	1, 2
Vibrio cholerae non-O1[b]	Yes	Yes	1
Vibrio parahaemolyticus	Yes	Yes	1
Vibrio mimicus	Yes	Yes	1
Vibrio fluvialis	Yes	Yes	1
Vibrio furnissii	Yes	Yes	1
Vibrio hollisae	Yes	Yes	1
Salmonella typhi	Yes	Yes	2, 3
Salmonella (nontyphoidal)	Yes	Yes	2, 3
Campylobacter jejuni	Yes	Yes	2, 3
Escherichia coli	Yes	No	2, 3
Yersinia enterocolitica	Yes	No	2, 3
Clostridium botulinum	Yes	Yes	2, 3
Shigella	Yes	Yes	2, 3
Staphylococcus aureus	Yes	Yes	3
Hekminths			
Anisakis simplex	Yes	Yes	1
Other helminths	Yes	Yes	1
Viruses			
Poliovirus	Yes	No	2
Other picornaviruses	Yes	No	2
Norwalk/Snow Mountain/small round viruses (SRVs)	No	Yes	2
Enteral non-A, non-B, hepatitis	No	Yes	2
Hepatitis A	Yes	Yes	2, 3
Organisms That Cause Disease Most Often in Special Population Groups			
Vibrio vulnificus[d]	Yes	Yes	1
Rotavirus[e]	Yes	No	2
Listeria	Yes	No	1, 3
Organisms with Uncertain Roles as Foodborne Pathogens			
Aeromonas hydrophila[f]	Yes	Yes	1
Plesiomonas shigelloides	Yes	Yes	1
Edwardsiella tarda	Yes	No	1

[a](1) Harvest water/associated with naturally occurring aquatic bacteria; (2) harvest water/associated with fecal pollution; (3) associated with processing and preparation (cross-contamination or time/temperature abuse, infected food handlers).

[b]Causes gastroenteritis in normal, healthy hosts; can cause septicemia in persons in high-risk groups.

[c]Primarily of historical association in the United States, but remains a problem in some foreign countries and could affect imports.

[d]Illness usually confined to high-risk groups.

[e]Illness generally occurs in children under the age of 2; older persons are usually immune.

[f]*Aeromonas* can cause serious wound infections and septicemia; however, conclusive data on its role as a cause of gastroenteritis are lacking. Studies suggesting that it is a gastrointestinal pathogen have not implicated seafood as a risk factor for illness.

SOURCE: IOM, 1991.

rare or not reported due to lack of severity of symptoms (see Table 4-9) (IOM, 1991). The two principle pathogens of concern are *Salmonella* spp. and *Listeria monocytogenes*.

Salmonella is a bacterium of widespread occurrence in animals, especially in poultry and swine. Environmental sources of the organism include water, soil, insects, factory and kitchen surfaces, animal feces, raw meats and poultry, and raw seafoods. *S. typhi* and the paratyphoid bacteria normally cause septicemia and produce typhoid or typhoid-like fever in humans. Other forms of salmonellosis generally produce milder symptoms (Source: http://www.cfsan.fda.gov/~mow/chap1.html).

Listeria monocyotogenes is a bacterium that can cause a serious infection in humans called listeriosis. Foodborne illness caused by *L. monocytogenes* in pregnant women can result in miscarriage, fetal death, and severe illness or death of a newborn infant. Others at risk for severe illness or death are older adults and those with weakened immune systems. *L. monocytogenes* can grow at refrigerator temperatures and is found in ready-to-eat foods (Source: http://www.cfsan.fda.gov/~dms/adlister.html 2003).

Federal regulation prohibits the sale of any raw or cooked seafood products contaminated with any *Salmonella*, or cooked, ready-to-eat seafood products contaminated with any *L. monocytogenes* (CFSAN, 2001) (see Appendix Table B-4). The zero tolerance policy for *Salmonella* on any seafood product is historically based on concerns for unsanitary practices that contaminated a food after harvest. The presence of any *Salmonella* on seafood from freshwater or saltwater harvests is considered an adulterant. Inland aquacultural production can expose farmed seafood to *Salmonella* from other animal sources including neighboring wildlife. Koonse et al. (2005) evaluated both product and environments (source water and grow-out pond water) from shrimp aquaculture across six countries, and found a significant association between the concentrations of *Salmonella* and both fecal coliforms and *E. coli*. Nevertheless, the occurrence of seafoodborne salmonellosis is rare. Reported cases are usually the result of cross-contamination or unsanitary handling practices (Koonse et al., 2005). Proper sanitation that includes adherence to Hazard Analysis and Critical Control Point (HACCP) regulatory requirements for daily sanitary monitoring and records plus cooking of seafood appear to be adequately controlling *Salmonella* in seafood.

Likewise, proper sanitary practices and cooking temperature remain the primary control points to prevent potential illnesses due to contamination from particular types and amounts of *L. monocytogenes* (*Lm*) that have been found on certain seafood products (Gombas et al., 2003). The most likely vehicle of transmission is previously cooked and ready-to-eat (RTE) seafood products with prolonged refrigerated storage that could al-

low further growth of these more cold-tolerant pathogens. The incidence of reported illnesses for *L. monocytogenes* for all foods significantly declined by 32 percent from 1996 to 2005 (CDC, 2006a), and there are few reports involving seafood products confirmed by CDC.

Regulatory control of *C. botulinum* includes processing for canned products, reduced oxygen packaging, smoking, fermenting, and pickling (FDA, 2001a). The *C. botulinum* is destroyed by heat processing. Botulinum poisoning is rare and usually involves previously cooked and ready-to-eat (RTE) products that have not been properly heat processed. Through 2004, there have been no documented cases of botulism from any fresh seafood product regardless of packaging (Austin and Smith, 2006) with one exception. This involved a whole fresh fish including uncooked viscera, prepared and consumed in Hawaii (CDC, 1991). None of the 19 incidences of botulism cited by Bryan (1980) involved fresh fish. In addition, the CDC (2005a) reported no incidences of *C. botulinum* for foodborne illnesses cited.

The remaining bacteria with proven pathogenicity in seafood have not posed any significant risk beyond occurrences and causes recognized with other foods. The controls for these hazards are similar in terms of sanitation, proper cooking, and proper refrigeration. They currently pose no unique trend in occurrences that suggest increased exposure risk through seafood consumption.

Viruses

There are a large number of seafoodborne illnesses of unknown etiology generally classified as norovirusal. Evidence is lacking due to limitations in the methodology for culturing and enumerating viruses; further identification is difficult. Current controls rely on monitoring of harvest waters used in production of molluscan shellfish intended for raw consumption (ISSC, 2003a). Water classification or approval protocols rely on indicators associated with the presence of viruses rather than actual measures for a particular virus. Contamination of water with human fecal matter on or near oyster beds has resulted in shellfishborne "Norwalk-like" viruses (NLV) and hepatitis A (HAV) infections in consumers of raw oysters harvested from the contaminated waters (Kohn et al., 1995).

Monitoring of water for indicators associated with the presence of viruses remains the primary control for products to be consumed raw because most new post-harvesting processing methods, including irradiation, used to reduce *V* in raw oysters have not been proven effective for reduction of viruses. Improvements in water classification programs may include advancing methodologies using PCR-based identification and monitoring for viruses in water and seafood products.

Parasites

Consumption of raw or undercooked seafood products that had not been previously frozen has been implicated in certain human parasitic infections. Table 4-10 lists the parasites and seafood choices that have been involved in previous documented illnesses. Incidence of parasitic infection is far more common in regions of the world where raw consumption is more frequent (Table 4-11). Seafoodborne infections are more prevalent in these regions than in the United States due to agricultural practices and reliance on freshwater sources that support the life cycle of certain hazardous parasites (Rodrick and Cheng, 1989; Sakanari et al., 1995). Since their adoption, HACCP programs, which include specific controls to prevent parasite infections, suggested incidence levels were underreported and expected to increase as consumer trends favored more consumption of raw selections (Jackson, 1975; Olson, 1986; McKerrow et al., 1988). The American Gastroenterological Association (AGA) surveyed approximately 30 percent (996 members) of the active AGA practitioners located in coastal states along the Pacific, Atlantic, and Gulf of Mexico, areas prone to parasite exposure (Personal communication, G. Hoskins, FDA Office of Seafood, December 2005). Survey respondents (over 58 percent) estimated

TABLE 4-10 Parasites and Products Involved in Documented Incidences of Parasitic Infection

Fishborne parasites involved in human infections resulting from consumption[a]	Some raw and undercooked seafood dishes involved in parasitic infections for products and recipes that are not previously frozen[b]
• Tapeworms (Cestodes) *Diphyllobothrium latum* *Diphyllobothrium pacificum*	• Cold-smoked fish (low-temperature smoked fish) • *Ceviche* (raw fish in lime juice or other pickling) • "Drunken crabs" (crabs marinated in wine and pepper) • Dutch green herring (light pickled herring)
• Flukes (Trematodes) *Clonorchis sinensis* *Opisthorchis viverrini* *heterophyes heterophyes* *Metagonimus yokogawai*	• *Gravlax* (type of cold-smoked salmon) • Hawaiian *lomi lomi* (chopped raw salmon with bell peppers and tomatoes) • Japanese "salad" (raw fish, fresh lettuce, and soy sauce) • Pacific Island *poisson cru* (raw fish fillet in a coconut milk recipe)
• Roundworms (Nematodes) *Gnathostoma spinigerum* *Capillaria philippinensis* *Anisakis simplex* *Phocanema* spp.	• *Palu* (fermented fish head and viscera recipe) • Philippine *bagoong* (a fermented paste made from whole fish) • Sashimi (raw fish slices) • Sushi (raw seafood with rice and seaweed) • *Tako poki* (Japanese and Hawaiian raw squid or raw octopus dish)

SOURCES: [a]Higashi, 1985; FDA, 2001a; [b]Sakanari et al., 1995; FDA, 2001a.

TABLE 4-11 Estimated Annual Occurrence of Parasitic Infections Due to Consumption of Seafood, Based on Original Compilation by FDA

Parasite	Worldwide	USA	Source
Tapeworm	9,000,000	100,000	Bylund, 1982
Fluke	20,000,000	Relatively low	Rim, 1982
Roundworm	2000+	50	Higashi, 1985

SOURCE: As referenced in FDA, 1987.

the number of cases over 24 months during 1998–2000 at 38 parasitic infections, of which 17 were anisikiasis, 16 were diphyllobothriasis, and 5 were pseudoterranoviasis. In the final report, the AGA estimated the actual number of infections would likely be 270 cases. This survey is considered one of the most current estimates for seafoodborne parasite infections in the United States but as a single survey, it is also considered underreporting. Nevertheless, seafoodborne parasitic infections are not common in the United States.

The guidelines for seafood processing and handling that accompanied the FDA mandate for HACCP regulations introduced additional specific controls to further prevent seafoodborne parasitic infections (FDA, 2001a). The FDA identified seafood species of concern (Table 4-12) and controls for HACCP program compliance (Table 4-13). Cooking and freezing had previously been reported as effective methods to kill parasites in order to

TABLE 4-12 Seafood Identified by the FDA that Could Involve Potential Parasite Hazards If Consumed Raw and Not Previously Frozen

Bass, Sea	Herrings	Rockfish	Trevally
Caplin	Hogfish	Sablefish	Trout
Cobia	Jacks	Salmon[a]	Tuna[b]
Cod	Kahawai	Scad	Turbot
Corvina	Mackerels	Sea trout	Wolffish
Eelpout	Monkfish	Snapper	
Flounders,[a] Sole,	Mullet	Sprat	Octopus
Dab, and Fluke	Perch, Ocean	Thorny head	Squid
Grouper	Plaice	Tomcod	
Halibut	Pollock	Tongue sole	Snails

NOTES: The general market names can include numerous species from various locations. The original sources should be referenced for actual species identified.

[a]Includes wild and aquacultured sources if fresh fish or plankton used as feed.

[b]Only applies to small tuna species; excludes large tuna species such as the yellowfin, bigeye, bluefin, and albacore.

SOURCE: FDA, 2001a.

TABLE 4-13 FDA Recommended Controls to Reduce or Eliminate Potential Parasite Hazards from Seafood

Procedure	FDA Recommendation	Comment
Parasite Removal	Trimming away of suspect and identified portions and/or portions identified with candling	Not recommended as sole preventive method
Cooking	Heating of raw fish sufficient to kill bacterial pathogens	FDA Food Code (2005e) definition for cooked seafood is an internal product temperature of 145°F for 15 seconds
Freezing	Freezing and storing at –4°F or below for 7 days or freezing at –31°F or below until solid and storing at –31°F or below for 15 hours, or freezing at –31°F or below until solid and storing at –4°F or below for 24 hours	FDA's Food Code recommends these freezing conditions to retailers who provide fish intended for raw consumption

SOURCE: FDA, 2001a, International Food Safety Council (http://www.foodsafety.gov/ ~dms/sept/99-week1.html).

prevent infections (Bier, 1976; Deardorff and Throm, 1988; FDA, 2001a). The current HACCP program requires freezing for certain species intended for commercial use as sushi and related raw seafood products (FDA, 2001a). Given the widespread adoption of HACCP and infrequent incidence of reported infections, concern about parasitic infection may not be deterring consumers from raw seafood consumption. Consumers may still choose to consume raw seafood products that have not been frozen previously.

Naturally Occurring Toxins

Ciguatera and Scombroid

Ciguatera and scombrotoxin are the two most persistent seafoodborne toxicants (IOM, 1991). Ciguatoxins, acquired through the local environmental food chain prior to harvest, may involve a variety of toxins from certain dinoflagellates. Ciguatera arises in certain fish harvested from specific tropical to subtropical regions about South Florida, the Caribbean region, and Hawaii. Reports in Florida suggest there is no evidence for increasing incidence (Personal communication, R. Hammond, Florida Department of Health, Tallahassee, FL, December 2005) (see Table 4-14). These data do not distinguish harvest source, but they do identify the more probable species of concern. Occurrence involves recreational as well as commercial harvests. Risk of ciguatera may increase with illegal recreational sales (not subject to HACCP controls) and with increasing imports of certain fish from affected areas.

TABLE 4-14 Reported Incidences for Ciguatera and Scombroid in the United States and by Selected States

Years and Locations	Ciguatera		Scombroid Poisoning	
	Outbreaks	Cases	Outbreaks	Cases
1993–1997[a]	60 total	205 total	69 total	297 total
USA	Avg-12/year	Avg-41/year	Avg-14/year	Avg-59/year
1990–1998[b]				
Hawaii	73 total	260 total	46 total	287 total
	Avg-8/year	Avg-29/year	Avg-5/year	Avg-32/year
Florida	16 total	82 total	10 total	55 total
	Avg-2/year	Avg-9/year	Avg-1/year	Avg-6/year
Florida[c]				
1994	3	13	5	14
1995	2	4	6	55
1996	8	30	5	9
1997	9	30	4	11
1998	5	37	5	14
1999	5	21	5	19
2000	9	31	3	10
2001	5	27	8	20
2002	5	10	3	4
2003	3	5	6	35
	Avg-5.4/year	Avg-21/year	Avg-5.0/year	Avg-19/year

SOURCES: [a]Olson et al., 2000; [b]Huss et al., 2004; [c]Personal communication, R. Hammond, Florida Department of Health, Tallahassee, FL, December 2005.

Subsequent handling, storage, or cooking cannot substantially reduce the risk. The toxic dose and consumer susceptibility remain in question while regulatory controls simply call for avoidance of certain fish from suspect areas. Absence of testable material, errant recall, and consumer misnaming can confuse species identification in reported illnesses. Despite product claims for utility, there are no reliable test kits to screen for ciguatera due to limited specificity for the toxins (Hungerford, 2005). Species avoidance may be the best control to reduce the potential hazard (Lange et al., 1992; Lehane, 1999). Barracuda is a common culprit that should be avoided (Morton and Burklew, 1970). Federal regulations for controls of ciguatoxins advise against consumption of certain species, and avoidance of fish from harvest locations with prior evidence of occurrence (FDA, 2001a). This advice is compromised by lack of area designations, unpredictable changes in the local food chains, and fish migration. Future controls could involve species restrictions from designated areas.

Scombroid poisoning, also known as histamine poisoning, involves thermal abuse of certain fish resulting in elevated levels of histamine con -

centrations that can invoke allergic-type reactions in susceptible consumers of raw or cooked fish. Cooking does not diminish these toxins. The primary fish involved include tunas and mackerels from the *Scombridae* family of fish—thus the name—and related species mahi-mahi (*Coryphaena hippurus*), escolar (*Lepidocybium flavobrunneum*), and others. The common feature distinguishing these fish is a higher proportion of free amino acids, i.e., histidine, lysine, and ornithine, naturally occurring in the muscle tissue, which can be decarboxylated to histamine, cadaverine, and putrascine. This conversion is driven by temperatures that allow growth of certain bacteria to generate the decarboxylating enzymes. Although regulatory action levels for histamine content (<50 ppm) have been established to prevent illnesses, cadaverine and putrascine have the potential to cause illness even in the absence of histamine (FDA, 2001a). Inadequate cooling at the point of harvest is considered the primary problem, and subsequent abuse can increase the potential hazard. Temperature control from harvest until consumption is recommended by the FDA (2001a). In the United States, HACCP mandates thermal controls from harvest through processing; most illnesses which continue to appear involve recreational harvests and imports. The incidences of illness could increase as more supply of affected species is imported and the illegal sale of recreational fish is not addressed with pertinent enforcement.

Shellfish Toxins

Naturally occurring toxins that have been associated with illnesses resulting from the consumption of certain molluscan shellfish such as oysters, clams, and mussels harvested from locations with specific environmental conditions include:

- Paralytic Shellfish Poisoning (PSP)
- Neurotoxic Shellfish Poisoning (NSP)
- Diarrhetic Shellfish Poisoning (DSP)
- Amnesic Shellfish Poisoning (ASP)

The filter-feeding mollusks accumulate the toxins in their viscera from the waters harboring naturally occurring marine algae (phytoplankton) that produce the toxins. Occurrence has involved both domestic and imported marine mollusks from tropical and temperate waters, depending on the particular species of phytoplankton and water conditions. Recent international reports include a comprehensive assessment of the potential occurrences that warrant closer scrutiny of particular algal species in various locations (FAO/IOC/WHO, 2004).

Related illnesses are rare but poisoning from shellfish toxins can be severe and deadly. Cooking is not considered sufficient to control potential

toxic levels in seafood (FDA, 2001a). Regulatory monitoring programs have been effective; but new toxins and plankton blooms are emerging worldwide, particularly in areas less subject to surveillance. Incidences of toxicity could increase without controls, although the likelihood for an outbreak is low. Appendix Table B-4 identifies tolerances and action levels set by federal agencies for potentially problematic products.

Chemotherapeutants

Most aquaculture operations depend on the use of various chemotherapeutants to control infectious diseases (FAO/NACA/WHO Study Group, 1999; FDA, 2001a). Aquaculture initially relied upon the same antimicrobials employed for production of beef and poultry and other land-based farming. The resultant food safety concerns, as for land-based agriculture, include possible toxic residue in the edible portions, contributions to potential antibiotic-resistant diseases (for both animals and consumers), and concomitant issues involving environmental contamination. Although the volume of chemotherapeutants used in aquaculture is far less than for other medical practices and agricultural production, international aquacultural use with less scrutiny may increase. Product seizures due to the presence of chemotherapeutants in some imported farm-raised seafood have occurred. (Allshouse, 2003; http://www.fda.gov/ora/oasis/3/ora_oasis_i_16.html; http://www.fda.gov/ora/oasis/1/ora_oasis_i_16.html).

Compounds of concern have included chloramphenicol, nitrofurans, fluoroquinolone, malachite green, and others (Table 4-15). All of these antimicrobial/antifungal agents have been used at some time for aquacultural production in the United States, prior to the implemention of restrictions by federal agencies (FDA, 2005f). The established level of controls is zero toler

TABLE 4-15 Antimicrobial/Antifungal Agents Used at Some Time for Aquaculture Production in the United States

Illegal Antibiotic or Chemotherapeutant	Action Level Based on Detection Limit
Chloramphenicol	0.3 ppb
Nitrofurans	1.0 ppb
Malachite green	1.0 ppb
Fluoroquinolones	5.0 ppb
Quinolones (Oxolinic Acid, Flumequine)	10.0 ppb (oxolinic acid) and 20.0 ppb
Ivermectin	10.0 ppb
Oxytetracycline	2.0 ppm

NOTES: ppb = parts per billion; ppm = parts per million.
SOURCE: Personal communication, W. Jones, Food and Drug Administration, October 12, 2006.

ance, based on the most current limits for analytical detection (Hanekamp, 2003), which currently range in parts per billion (ppb) for residuals. Similar limits are in place in other developed nations that depend on seafood imports (Kulkarni, 2005).

The actual food safety risk resulting from the use of chemotherapeutants in aquaculture has been difficult to assess for lack of surveillance for the types and extent of use, and uncertainty about the hazards (FAO/NACA/WHO Study Group, 1999; Caprioli, 2000; Hanekamp, 2003). Toxic effects from the very low, ppb levels encountered in some aquacultured foods have been questioned (Hanekamp, 2003). Some studies have suggested probable transmission of antimicrobial-resistant bacteria in aquacultured food (Ervik et al., 1994; Weinstein et al., 1997; Angulo, 1999; Duran and Marshall, 2005). Yet recent reviews compiled by the Institute of Food Technologists (ITF, 2006) indicate the use of "chemical and biological antimicrobials and physical preservation systems has been remarkably successful in providing safe foods and has not been compromised by the occurrence of resistent microorganisms." The list of chemotherapeutants approved for use in aqua culture is limited and there is strict monitoring of finished products.

Analytical procedures for detecting chemotherapeutants in the ppb range are expensive and time-consuming which may deter routine sampling of aquacultured products. Prevention of illegal use of chemotherapeutants may be achieved through education and development of "best aquaculture practices" (Florida Department of Agriculture and Consumer Services, 2005). Programs are emerging to address this need in both domestic (Otwell et al., 2001; ACC, 2004) and international settings (http://www.gaalliance.org/resp.html; http://www.aquaculturecertification.org/index.html; Otwell et al., 2001). Agencies in the United States have developed programs to advance approval and use of additional chemotherapeutants, as exemplified by the recent recognition for use of florfenicol in catfish farms (FDA, 2005b).

Seafood Allergens

According to the recommended definitions for adverse food reactions (Anderson, 1986; O'Neil and Lehrer, 1995; Adverse Reactions to Food Committee, 2003), a seafood allergy involves an immunologic reaction following exposure to a seafood. The true prevalence of seafood allergies in the United States is unknown and difficult to estimate (Bush, 1995), although they remain among the most common food-induced allergies (Taylor and Bush, 1988; O'Neil et al., 1993; Hefle, 1996) (see Table 4-16). They are more commonly associated with adults (Taylor and Bush, 1988). In general, the prevalence of food allergies is overestimated (Sampson, 1992; O'Neil and Lehrer, 1995) for lack of proper diagnosis or confusion with other food sensitivities, but actual occurrence of seafood allergies is estimated

TABLE 4-16 Most Commonly Implicated Foods in Food Allergy Listed by Most Common Age Group Involved According to the Original Source

Adults	Children
Peanuts	Cow milk
Tree nuts	Eggs
Soybeans	Soybeans
Fish	Peanuts
Crustaceans	Wheat
	Tree nuts

SOURCE: Hefle, 1996.

to affect less than 2 percent of the US population (Hefle, 1996). Of this group, 280,000 to 500,000 consumers may be at risk for developing allergic reactions to seafood (Lehrer, 1993; O'Neil and Lehrer, 1995). Since exposure is the mediating factor, occurrence tends to be more prevalent near coastal regions and will likely increase as per capita seafood consumption increases (Lehrer, 1993; O'Neil et al., 1993; O'Neil and Lehrer, 1995).

Exposure can involve ingestion, inhalation (of vapors), or product handling for consumption or occupation. Likewise, potential exposure can be hidden as the presence of the particular seafood item may not be obvious or expected due to an unidentified ingredient or misidentified ingredients (i.e., fish-based surimi used in a "crab" salad). It can also result from cross-contamination of nonallergenic foods from handling either with the same improperly cleaned utensils or through subsequent cooking in the same containers or cooking media (frying oil or boiling water) as seafood (O'Neil and Lehrer, 1995; Hefle, 1996).

Similar food intolerances that are misidentified as a seafood allergy can involve an abnormal physiological or sensitive response to components accompanying the seafood (Taylor and Nordlee, 1993). Exposure to sulfiting agents is a common suspect. Sulfites are among the most widely used food additives in the food industry (IOM, 1991; Otwell et al., 2001). They are approved for use in preventing discoloration caused by indigenous enzyme activity on shrimp, lobsters, and other crustaceans (FDA, 2001a). If the sulfite residual on certain foods is excessive and not bound to the food matrix, exposure for certain asthmatic consumers could result in serious reactions. The prevalence of such reactions has been estimated at approximately 3.9 percent of asthmatic patients (Bush et al., 1986). Adverse reactions to sulfite residuals on properly treated seafood are rare, since the sulfiting agents are usually bound to the food protein matrix and are not readily released in the throat or nasal areas during consumption. Regulatory HACCP mandates

also specify requirements for distinct labeling of any seafood exposed to sulfiting agents.

Consumer awareness and labeling remain the most effective measures to prevent exposure to seafood that could elicit a food sensitivity response. Commercial practices for dual processing or preparation of other foods in facilities or with utensils used for seafood must avoid potential cross-contamination that could result in unanticipated exposures. Requirements to identify seafood or any use of seafood ingredients, as well as certain food additives, have been emphasized by the HACCP mandate (FDA, 2001a) requiring appropriate hazard analysis to identify any potential food sensitivity risks controlled through proper cleaning, product segregation, or product identification in order to prevent a potential hazard.

Adverse Effects Associated with Omega-3 Supplementation

While there is extensive research suggesting health benefits from the consumption of EPA/DHA found in fish oils, there are also data that indicate that overconsumption of fish oils could have adverse consequences. Evidence suggests that EPA and DHA may increase bleeding time, specifically by reducing platelet aggregability, and prolonged bleeding times in humans whose diets were supplemented with fish oil have been observed (e.g., Jensen et al., 1988; Rodgers and Levin, 1990; Harris et al., 1991). After reviewing this literature, FDA concluded that prolonged bleeding is not a significant risk at levels of consumption of up to 3 grams per day of EPA and DHA (Source: http://www.cfsan.fda.gov/~dms/ds-ltr11.html). This conclusion was the basis for FDA's recommendation, which remains in force, that consumption of EPA and DHA combined should be limited to 3 grams per day, of which 2 might come from supplements.

Other potentially adverse effects of excessive consumption of fish oils include reduced glycemic control among diabetics, increased levels of low-density lipoprotein (LDL) cholesterol among diabetics and hyperglycemics, and immunosuppressive effects. FDA determined that limiting consumption of EPA and DHA to 3 grams per day would protect against these effects also.

Since some contaminants that may be found in seafood are lipophilic, including PCBs, DDT and its metabolites, DLCs, and polyaromatic hydrocarbons (PAHs), they may tend to concentrate in the fish oil. It is important to recognize that dietary supplements, including fish oils sold as supplements, are subject to the same regulations regarding adulteration as are conventional foods. A food is considered adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to health" or if it "has been prepared, packed, or held under insanitary condi-

tions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health" (21 USC 342(a)(1) & (4)).

Fish-oil supplements are regulated by FDA under the provisions of the Dietary Supplement Health and Education Act (DSHEA). This law provides that no FDA safety notification is needed for dietary supplement ingredients that were already on the US market prior to October 15, 2004. Fish oils are "grandfathered" under this provision, and thus there are no standards of identity for commercial fish-oil dietary supplements. Further, there is no provision under any law or regulation that requires a firm to disclose to FDA or consumers the information they have about the safety or purported benefits of their fish-oil products.

FDA is, however, empowered to remove from the market any fish-oil supplement that is not of adequate purity to ensure consumer safety under normal conditions of use. Since FDA has limited resources to analyze the composition of food products, including dietary supplements, it focuses these resources first on public health emergencies and products that may have caused injury or illness. Enforcement priorities then go to products thought to be unsafe or fraudulent or in violation of the law.

Fish-oil products, as opposed to fish themselves, can be processed to remove undesirable constituents. An industry trade association, the Council for Responsible Nutrition, established voluntary standards for its members in October of 2002. These standards limit concentrations of contaminants in fish-oil products as follows:

- DLCs: δ2 pg TEQ/g
- PCBs: δ0.09 ∝g/g
- Heavy metals (lead, cadmium, mercury, arsenic): all <1 ∝g/g

Data submitted to FDA by the National Fish Meal and Oil Association on pesticide and PCB analysis in fish oil, conducted under Title 21, Code of Federal Regulations, Parts 109 and 509 "Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed," indicated that multiple samples of menhaden and fish oil (refined and crude) did not contain detectable levels of a panel of pesticides, PCBs, and diox - ins (Source: http://www.fda.gov/ohrms/dockets/dailys/02/Jul02/070202 / 99p-5332_sup0003_01_vol1.pdf).

Summary of Evidence

In summary, while certain hazards associated with specific species (e.g., scombroid poisoning) and lack of compliance with food safety guidelines (e.g., eating raw molluscan shellfish) persist, reviews of reported seafood - borne illnesses indicate that more acute seafood safety hazards are not

increasing. This trend seems to be due in part to the food safety control measures mandated since 1997 (e.g., HACCP and monitoring of sanitation control procedures); the new labeling requirements providing educational support; and specific management plans implemented by regulatory and industry partnerships to address the more serious illnesses associated with consumption of raw molluscan shellfish. However, the potential for misuse of chemotherapeutants in domestic and imported aquaculture products is a source for concern about the presence of toxins and increased antimicrobial resistance in seafood, particularly in light of increasing dependence on aquacultured products.

CHAPTER CONCLUSION

The committee's review of evidence on risks associated with consumption of seafood drew on current research reports and reviews, published reviews from stakeholder groups, invited presentations made to the committee, and correspondance with experts in areas relevant to the statement of work. One component of the committee's charge was to identify and prioritize the potential for adverse health effects from both naturally occurring and introduced toxicants in seafood. The conclusion from the committee's review of evidence is that, among chemical contaminants, methylmercury presents as a greater concern for adverse health effects, whereas the risk associated with dioxins and PCBs in seafood remains uncertain due to both the availability of evidence and the strength of the findings, and that microbial hazards, particularly those associated with handling and cooking practices, pose a more controllable yet persistent seafood-related risk from the standpoint of public health concerns.

FINDINGS

1. Levels of contaminants in seafood depend on several factors, including species, size, harvest location, age, and composition of feed. Methylmercury is the seafoodborne contaminant for which the most exposure and toxicity data are available; levels of methylmercury in seafood have not changed substantially in recent decades. Exposure to dioxins and PCBs varies by location and vulnerable subgroups (e.g., some American Indian/Alaskan Native groups living near contaminated waters) may be at increased risk. Microbial illness from seafood is acute, persistent, and a potentially serious risk, although incidence of illness has not increased in recent decades.

2. Methylmercury is the seafoodborne contaminant for which the most comprehensive exposure and toxicity data are available for the purpose of deriving quantitative estimates of the risks.

3. The evidence pertaining to the health risks associated with consumption of seafoodborne contaminants derives from observational studies, primarily cross-sectional and prospective cohort in design. The use of a randomized clinical trial to evaluate contaminant risks would be unethical.

4. The metrics used to characterize the risks associated with consumption of seafoodborne contaminants, such as the reference dose, are useful in identifying a contaminant intake level that is considered, based on available data, to be "without an appreciable risk of deleterious effects during a lifetime." Such metrics are not useful, however, in characterizing the increase in risk that is associated with intake levels that are above the reference dose. The dose-response modeling used to identify the BMD and BMDL could be used to characterize the risks although it is important to recognize that the estimates will be influenced by the assumptions made regarding, for example, the appropriate dose-response function.

5. Reference levels for the intake of contaminants, such as the RfDs for methylmercury and dioxin-like compounds, can be misinterpreted as "bright lines," i.e., that intakes above the level are "harmful" and intakes below the level are "safe."

6. With regard to trends in population exposures to chemical contaminants,

a. On the basis of nationally representative data on the US population, the median blood mercury level was unchanged over the period 1999–2002.

b. Exposures to PCBs and dioxin-like compounds are decreasing on a population basis, but exposures can vary greatly according to geographic region and consumption patterns so that particular subgroups of the population could be at increased risk.

7. Increased methylmercury exposure might be a risk factor for adult cardiovascular toxicity, although the data available are not extensive and uncertainties remain.

8. Considerable uncertainties are associated with estimates of the health risks to the general population from exposures to MeHg and POPs at levels present in commercially obtained seafood. The available evidence to assess risks to the US population is incomplete and useful to only a limited extent.

9. Estimates for trends in chemical contaminants in the seafood supply depend on harvest location and products of concern.

a. Concerns regarding levels of PCBs and DLCs in certain aquacultured products can be addressed by means of further scrutiny of feed content and uses.

b. The levels of methylmercury in marine seafood do not appear to have changed systematically in recent decades.

10. New potential chemical-associated risks continue to be identified

in seafood and other foods (e.g., polybrominated diphenyl ethers and other persistent organic pollutants), although inadequate data on exposure, toxicities, or both make it difficult to define the dimensions of the potential risks.

11. Consumers are exposed to a complex mixture of dietary and nondietary contaminants whereas most studies of the risks associated with seafood focus on a single contaminant. The extent to which such co-exposures might affect the toxicity of seafoodborne contaminants is largely unknown. Similarly, few data are available on the extent to which beneficial components of seafood, such as selenium and omega-3 fatty acids, might mitigate the risks associated with seafoodborne contaminants.

12. Reported seafoodborne illnesses indicate acute hazards are not increasing, but certain hazards associated with specific species and consumer preference (e.g., eating raw molluscan shellfish) persist.

13. Increased dependence on aquacultured and imported products is raising concerns for certain potential hazards.

a. Use of illegal chemotherapeutants in certain aquaculture operations.

b. Various microbial and chemical contaminants in products subject to limited regulatory surveillance.

RECOMMENDATIONS

Recommendation 1: Appropriate federal agencies (the National Oceanic and Atmospheric Administration [NOAA], the US Environmental Protection Agency [US EPA], and the Food and Drug Administration [FDA] of the US Department of Health and Human Services) **should increase monitoring of methylmercury and persistent organic pollutants in seafood and make the resulting information readily available to the general public.** Along with this information, these agencies should develop better recommendations to the public about levels of pollutants that may present a risk to specific population subgroups.

Recommendation 2: Changes in the seafood supply (sources and types of seafood) must be accounted for—there is inconsistency in sampling and analysis methodology used for nutrient and contaminants data that are published by state and federal agencies. Analytical data is not consistently revised, with separate data values presented for wild-caught, domestic, and imported products.

Research Recommendations

Recommendation 12: More complete data are needed on the distribution of contaminant levels among types of fish. This information should be

made available in order to reduce uncertainties associated with the estimation of health risks for with specific seafoodborne contaminant exposures.

Recommendation 13: More quantitative characterization is needed of the dose-response relationships between chemical contaminants and adverse health effects in the ranges of exposure represented in the general US population. Such information will reduce uncertainties associated with recommendations for acceptable ranges of intake.

Recommendation 14: In addition, the committee recommends more research on useful biomarkers of contaminant exposures and more precise quantitative characterization of the dose-response relationships between chemical contaminants and adverse health effects in the ranges of exposure represented in the general US population, in order to reduce uncertainties associated with recommendations for acceptable ranges of intake.

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5

Analysis of the Balancing of Benefits and Risks of Seafood Consumption

The committee's task included a charge to develop a decision path appropriate to the needs of US consumers for selecting seafood in ways that balance nutritional benefits against exposure risks. In the committee's judgment, there are three distinct steps in the process of designing consumer guidance about balancing benefits and risks in making seafood consumption decisions (see Box 5-1). After a brief overview, this chapter addresses the first step in the process: the scientific assessment and balancing of the benefits and risks of seafood consumption. Subsequent chapters address the second and third steps in the process.

The scientific assessment and balancing of the benefits and risks of seafood consumption contained in this chapter is based on the evidence presented in Chapters 3 and 4. The committee found that its ability to quantify benefit-risk trade-offs was limited from the benefit side (e.g., the quantitative link between eicosapentaenoic acid/docosahexaenoic acid [EPA/DHA] consumption and health benefits), the risk side (e.g., the quantitative risk of methylmercury [MeHg] exposure for adult men), and in terms of benefit-risk interactions. Because of this uncertainty, the committee concluded that it was not feasible to present a quantitative benefit-risk assessment and balancing. Thus it relied on its expert judgement to produce a qualitative scientific benefit-risk analysis and balancing of the benefits and risks of seafood consumption.

INTRODUCTION

Advice to consumers about balancing the benefits and risks of seafood consumption must be based on the best available scientific information. The

BOX 5-1
A Three-Step Process to Design Consumer Guidance on Balancing Benefits and Risks Associated with Seafood Consumption

Step 1: Scientific benefit-risk analysis and balancing of the benefits and risks (including attention to characteristics [e.g., age, sex] that distinguish target populations and the effects of potential food substitutions made by consumers).

Step 2: Empirical analysis of consumer perceptions and decision-making (understanding decision contexts and their variability; eliciting input from consumers regarding how they perceive and make choices) (see Chapter 6).

Step 3: Design and evaluation of the guidance program itself (including the format of guidance, program structure and media [e.g., brochures, websites, public meetings or programs, radio spots, point-of-purchase displays, hotlines], and the combination of communication products and processes) (see Chapter 7).

scientific assessment and balancing of the benefits and risks associated with seafood consumption is a complex task. Diverse evidence, of varying levels of completeness and uncertainty, on different types of benefits and risks must be combined to carry out the balancing required in the first step in designing consumer guidance. To produce coordinated benefit-risk advice requires combining expertise from several disciplines, as this committee has done.

In other settings, balancing benefits and risks has been approached through a variety of summary metrics. These include: Quality Adjusted Life Years (QALYs), which combine the quantity and quality of life; Disability Adjusted Life Years (DALYs), which are the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability (Gold et al., 2002); monetary measures; utility measures (estimates from multi-attribute utility analyses); and deliberative decision-making exercises. These decision-making exercises focus on trade-offs as a means to inform policymakers about, first, decision attributes of different choices and, second, development of means-ends objectives networks that illustrate values people want to achieve and how they think those can best be achieved (Gregory and Wellman, 2001; Gregory et al., 2001). However, in the case where benefits and risks have an outcome on the same endpoint,

such as MeHg and EPA/DHA impacts on neurologic development, it is not necessary to artificially link the benefit and risk through a separate construct such as QALYs.

In light of uncertainty in the scientific information associated with both nutrient intake and contaminant exposure from seafood, it is the committee's judgment that no summary metric adequately captures the complexity of seafood benefit-risk trade-offs. The committee outlined an approach to balance benefits against risks, conducted an analysis of the trade-offs, and considered additional factors that informed each in order to produce a decision framework that incorporates benefit and risk analysis. Over time, the process of balancing benefits and risks must be iterative, with systematic, objective reviews following strict profiles, and updates and reinterpretation as new evidence is developed. This can be accomplished through the convening of an expert group such as this committee or through the organization of expertise within federal agencies to provide comprehensive benefit-risk analysis rather than piecemeal benefit-by-benefit and risk-by-risk analysis.

APPROACH TO BALANCING BENEFITS AND RISKS

In developing its approach to balancing benefits and risks, the committee considered previous approaches developed to analyze scientific evidence and balance benefits and risks: two of these approaches are risk-risk or risk-trade-off analysis and risk relationship analysis.

"Risk-risk" or "risk-trade-off" analysis was developed as a means of further evaluating regulatory and other actions targeted at reducing a specific risk (Gray and Hammitt, 2000; Hammitt, 2000; IOM, 2003). This approach emphasizes that in reducing a targeted risk, it is possible that other risks would be created or increased. This approach also provides a means for considering multiple countervailing risks that may indicate whether it is either riskier to remediate a problem or take no action.

"Risk-relationship" analysis goes a step further, recognizing the possible existence of ancillary benefits as well as countervailing risks that may result from adopting a particular risk-management option (IOM, 2003). For example, efforts to reduce a contaminant in a specific food product may pose a countervailing risk if the efforts make a nutrient-rich food too expensive for some consumers to afford. In addition, the higher price of the product could cause consumers to switch to alternative products that pose similar or higher risk from the same or other contaminants. However, if the product is high in a food component that is unhealthful, then a switch away from it may generate ancillary benefits such as reduced risk for chronic disease.

The committee concluded that its charge goes an important additional step beyond risk-relationship analysis. Risk-relationship analysis starts with a targeted risk reduction and attempts to identify significant potential

ancillary benefits and countervailing risks that may affect the risk reduction actually achieved through a risk management option. In the case of designing guidance to consumers on selecting seafood, there is a suite of benefits and risks that needs to be simultaneously targeted and considered. The target of analysis is the overall effect of seafood selection and consumption decisions, and not reduction of a specific risk or enhancement of a specific benefit. For this reason, the construct of ancillary benefits and countervailing risks is not applicable.

For Step 1 of the three-step process, the committee developed the approach of *benefit-risk analysis* to design consumer guidance on balancing benefits and risks associated with seafood consumption, shown in Box 5-1. The approach points to the types of information needed to improve benefit-risk decisions. An expert judgment technique is one approach to this task, given the uncertainty in the data that supports the evidence on benefits and risks. In its deliberations, the commmittee adapted a four-part protocol based on previous work (IOM, 2003) to complete Step 1, scientific benefit-risk analysis, in the process of designing seafood guidance.

Part A. Identify and determine the magnitude of the benefits and risks associated with different types of consumption for the population as a whole and, if appropriate, for specific target populations.

Part B. Identify the benefits and risks that evidence suggests are important enough to be included in the balancing process used to develop consumption guidance for the population as a whole and, if appropriate, for specific target populations.

Part C. Evaluate changes in benefits and risks associated with changes in consumption patterns. The magnitude of the changes depends on the magnitude of exposure to specific agents, either nutrients or contaminants, and how the magnitude of the response varies in relation to changes in intake or exposure.

Part D. Balance the benefits and risks to arrive at specific guidance for healthy consumption for the population as a whole and, if appropriate, for specific target populations.

SCIENTIFIC BENEFIT-RISK ANALYSIS FOR SEAFOOD CONSUMPTION

Part A. Identify and Determine the Magnitude of the Benefits and Risks

The committee identified the range of benefits and risks that the evidence suggests are important to balance in developing seafood choice guidance. The nutritional benefits of seafood include: it is a source of protein that is low in saturated fat, and contains several essential micronutrients, especially

selenium. Seafood also is a primary source of the omega-3 fatty acids EPA and DHA. The evidence detailed in Chapter 3 indicates that consumption of seafood and/or EPA/DHA by pregnant females may provide benefits to their developing fetuses. Infants receiving EPA/DHA either from breast milk or supplemented formula may benefit in terms of neurological and visual development. Similarly, there is evidence that consumption of fish is associated with cardiovascular benefits in the general population.

These benefits must be balanced against risks to health, as reviewed in Chapter 4, from exposure to chemical and/or microbial contamination that may be present in some seafood available to US consumers. The best-characterized risk from chemical contamination of seafood is from methylmercury, a potent neurotoxin. Thus, the population groups at greatest risk from exposure to contaminants in seafood are the developing fetus, infants, and young children. As discussed in Chapter 4, a Reference Dose (RfD) has been established for methylmercury on the basis of developmental tests in children born to mothers from populations where seafood is a major part of their diets. At the same time, evidence suggests the fetus and infant may be among the principal beneficiaries from certain nutrients in seafood. Evidence available on levels of MeHg that may be detrimental to nonpregnant adults has not allowed the formulation of a similar reference dose based on risks to these population segments.

In establishing their joint advisory targeted at pregnant women and children, the US Environmental Protection Agency (US EPA) and Food and Drug Administration (FDA) examined potential intakes of MeHg that would occur in pregnant women given consumption patterns using various available commercial sources of seafood. If predatory fish high in mercury were avoided completely, they concluded that up to 12 ounces of fish (four 3-ounce servings per week) could be consumed without exceeding the RfD dose that has been established with studies in populations of women consuming substantial amounts of seafood (US EPA/FDA, 2004) (see Chapter 4). Though the committee recognized that the RfD was not a "bright line" that established a firm cutoff for risk, the FDA/EPA fish advisory provides reasonable guidelines for pregnant women to consume seafood in amounts that may confer benefit without significantly increasing risk. There is little evidence available about levels of methylmercury that may be detrimental to other segments of the population.

Risks from other contaminants in seafood are, comparatively, less well-characterized than methylmercury. Contamination from persistant organic pollutants (POPs) has been characterized at exposure levels that result from industrial releases or occupational exposure, and for fish-consumers in geographic areas where contaminants are more concentrated. However, at lower levels of exposure there is less information available on adverse health effects. In addition, levels of dioxin-like compounds (DLCs) and polychlori-

nated biphenyls (PCBs) vary considerably among different types of seafood, with relatively higher levels found in fatty compared to lean fish. There is limited available data on levels of DLCs and PCBs in seafood and terrestrial animal products, but levels in seafood may on average be comparable to or higher than those in red meat and full-fat dairy products (IOM, 2003). Risks from microbiological hazards will vary, largely according to handling and preparation methods (e.g., consuming raw rather than cooked seafood).

Part B. Identify Important Benefits and Risks in the Balancing Process

Although some guidance applies to all groups, e.g., general nutritional benefits and microbial risks, a key conclusion of the committee's deliberations is that the evidence in regard to the benefits and risks associated with seafood consumption varies in important ways across target populations. Thus, guidance should be tailored to these populations. Equally important is that everyone in the population be covered by specific guidance.

Given the current evidence reviewed in this report, decisions about seafood consumption for the general population consuming commercially available seafood fall into four target populations: (1) females who are or may become pregnant, and those who are breastfeeding; (2) infants and children up to age 12; (3) adolescent males, adult males, and females who will not become pregnant; and (4) adult males and females at risk for coronary heart disease. During the committee's initial deliberations, adult males and females with a *history* of coronary heart disease were considered as a separate target population. However, recent evidence suggests that the guidance for these persons is not different from that for adult males and females at risk of coronary heart disease.

The committee recognizes that there are additional groups of consumers for whom guidance must be further tailored, such as subsistence and recreational fishers. However, designing guidance for these groups requires further separate, specific analyses of benefit and risk impacts. As noted in Chapter 4, to date there is little known about the impact of high seafood consumption, beyond that previously reported on neurological development in fetuses and young children. The committee decided there was insufficient evidence to set an upper limit on the amount of seafood consumed each week by the general public, except where research supports such recommendations.

Part C: Evaluating Changes in Benefits and Risks Associated with Changes in Consumption Patterns

The committee conducted several analyses to evaluate and understand changes in benefits and risks that may be associated with changes in con-

sumption patterns that could occur due to the type of guidance provided to consumers. The extent of these changes depends on the magnitude of exposure to a specific agent—either nutrients or contaminants—and how the change of the response varies in relation to changes in intake or exposure. These analyses and their implications for the design of consumer guidance are discussed below.

Substitution Impact on Selected Nutrients

The committee reviewed the impact of substitution in two ways. First, it considered the quantity of various foods that would need to be eaten to provide approximately 100 mg of EPA/DHA. Next, the committee reviewed the differences in selected nutrients contributed by 3-ounce portions of various meat, poultry, and seafood sources. While recognizing that there are many species of seafood, those chosen for this analysis represent the most frequently eaten types in the United States (e.g., shrimp, tuna, and salmon). The committee further considered the contribution of specific nutrient levels (e.g., EPA/DHA in species of salmon) in developing consumer guidance (see Figures 7-5 through 7-8b). The committee looked at the specific impact of food choice trade-offs involving calories, saturated fat, EPA/DHA, selenium, and iron. The committee did not consider potential impacts of seafood choices on other vitamins and minerals because it relied on the conclusions already drawn by the Dietary Guidelines Advisory Committee (DGAC) that the substitution of two servings of seafood for two servings of animal protein foods would not substantially impact the vitamin and mineral content of the diet of the average American consumer (DGAC, 2005).

Figure 5-1 compares the number of portions (servings) from various animal foods that an individual would need to select to consume 100 mg EPA/DHA. The graph shows that to achieve a similar EPA/DHA intake level, a smaller amount of a high-EPA/DHA seafood, e.g., salmon, is needed compared to other food sources. This difference (consuming higher quantities of food to achieve an equivalent intake of EPA/DHA) is significant because of the corollary increase in total caloric and saturated fat intake from most other foods (see Table 5-1). Nonanimal sources of omega-3 fatty acids are not included in this comparison.

Weighing benefits against risks from consuming seafood needs to be considered in the context of the total diet. Table 5-1 highlights nutritional factors that may influence the assessment of the benefits and risks associated with seafood consumption by comparing nutrient levels from one 3-ounce serving of different animal protein foods commonly consumed by Americans. The foods selected as examples include lean (10 percent fat) and fatty (20 percent fat) beef, chicken (< 5 percent fat), shrimp, and canned tuna, both light and white (albacore). Preparation methods chosen were the low-

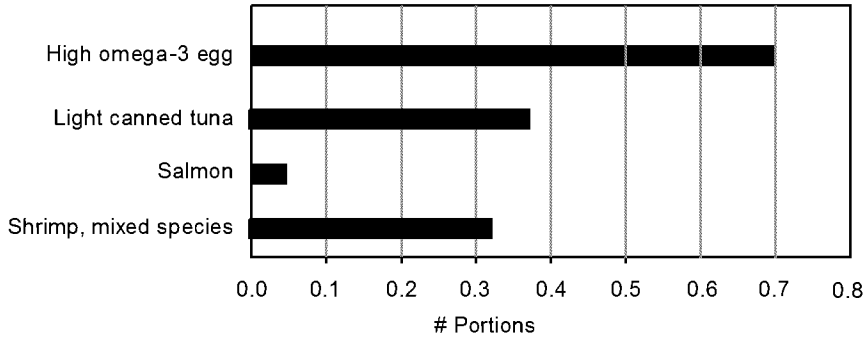

FIGURE 5-1 Number of portions* needed to consume 100 mg EPA/DHA in selected animal protein foods.
*Portion size = 100 g uncooked for all foods except eggs (~85 g = 1 egg).
SOURCE: US Department of Agriculture [USDA] *Nutrient Database, Release ↑↑*. [Online]. Available: http://www.nal.usda.gov/fnic/foodcomp/Data/SR18/sr18.html; Sindelar et al., 2004.

est in fat (e.g., baked). It should be noted that any adjustments to the total diet to accommodate the addition of one food choice can be balanced by decreases in other choices (e.g., higher and lower energy foods). Benefits associated with selecting a specific food may be counterbalanced by risks associated with food preparation methods, e.g., the introduction of more calories and saturated fat by frying fish.

Although most seafood choices are lower in fat than animal meats, poultry, and eggs, the impact on energy and saturated fat intake depends on the particular substitution being made. For example, although salmon provides less energy and saturated fat than either of the beef choices shown in Table 5-1, it is higher in both these nutrients than chicken or eggs. Nonetheless, the substitution of salmon for all other animal protein sources results in increases in EPA/DHA intake levels (from 0.0 to 1.8 g). In fact, the substitution of any of the seafood choices listed in Table 5-1 for any of the beef, chicken, or egg choices results in more EPA/DHA and selenium. Finally, it can be seen that salmon and tuna are generally lower in iron than beef, which may be a consideration for pregnant females, other females of childbearing age, and individuals at risk for iron deficiency anemia.

Substitution Impact on Selected Contaminants

There are limited available data from which to construct scenarios of the risk impacts of substituting seafood for other animal protein sources. Contaminants for which there are reported values are methylmercury and

dioxins and DLCs. Food choices are compared in Table 5-1. For a 57 kg reference female to make a weekly selection of two 3-ounce servings of seafood and not exceed the RfD level for methylmercury (5.7 μg MeHg per day) requires that no more than one of those selections be white (albacore) tuna. In contrast, levels of DLCs in two 3-ounce servings of white (albacore) or light canned tuna or salmon do not exceed target exposure limits. Making a trade-off of 20 percent fat beef for salmon will not decrease the exposure levels to DLCs, although it will for MeHg. Selecting light canned tuna in place of white (albacore) tuna will decrease exposure levels to both MeHg and DLCs, but will also significantly decrease intake levels of EPA/DHA.

Uncertainties in Substitution Analysis

The substitution analyses presented above are based on nutrient and contaminant values. However, there are several sources of uncertainty in the estimates of these nutrient and contaminant values. Mean estimates of nutrients represent best estimates of the value one would expect to find in any specific case. A common indication of how much one can expect individual values to vary from the mean is a confidence band, the calculation of which is based on the individual sample values observed. The committee did not have access to individual sample values or estimates of the variability in those for the estimates reported in Table 5-1.

Table 5-2 characterizes some of what is known about the data from which the estimates in Table 5-1 were derived (i.e., their provenance). As Table 5-2 illustrates, sample sizes and ages vary tremendously. While it is difficult to determine just how significant it is, variability in sample sizes and approaches, together with changes over time in analytical methods (Igarashi et al., 2000; Siddiqui et al., 2003) and in feed (e.g., reductions in the use of fishmeal in poultry feed) are noteworthy sources of uncertainties (Barlow, 2001). The EPA/DHA levels in chicken provide a case in point.

Comparison of the estimates in Table 5-1 with those from other sources also suggests considerable variability and uncertainty. Hamilton et al. (2005) illustrate that levels of omega-3 fatty acids in salmon vary by source. Using samples of farmed, wild, and store-purchased salmon from a large number of locations, they estimated that omega-3 fatty acid levels in farmed Atlantic salmon are more than twice as high as in salmon from other sources. Further, their estimate of omega-3 fatty acid levels in farmed Atlantic salmon is almost twice as high as that shown in Table 5-1.

Importantly, specific population subgroups, e.g., Native Alaskans who previously relied on seafood and marine mammal consumption and followed advice to decrease their intake of these foods to reduce the risks associated with exposure to contaminants, suffered negative consequences in overall nutrition (Wheately and Wheately, 1981; Murphy et al., 1995;

TABLE 5-1 Estimated Levels of Selected Nutrients and Contaminants per 3-ounce Cooked Serving of Seafood and Animal Food Choices

	Energy		Saturated Fat		Cholesterol		EPA/DHA	
Food Choice	# Data points	kcal/3 oz[a,*]	# Data points	g/3 oz[a,*]	# Data points	mg/3 oz[a,*]	# Data points	g/3 oz[a,*]
Salmon	N/A	175	N/A	2.1	2	54	2	1.8
White (albacore) tuna	N/A	109	N/A	0.7	N/A	36	N/A	0.7
Light tuna	N/A	99	N/A	0.2	3	26	5	0.2
Shrimp	N/A	84	N/A	0.2	0	166	11	0.3
Beef, 20% fat	N/A	230	35	5.8	36	77	N/A	0
Beef, 10% fat	N/A	184	35	4	36	72	N/A	0
Chicken[i]	N/A	140	N/A	0.9	0	72	N/A	0.03
Egg[i]	N/A	132	N/A	2.8	7	360	37	0.04
Point of Reference	EER[1,d] Men = 2700 kcal/day Women = 2100 kcal/day Pregnant = +300 kcal/day Lactating = +500 kcal/day		As low as possible while consuming a nutritionally adequate diet[1]		As low as possible while consuming a nutritionally adequate diet[1]		AI of total omega-3[1,e] Men = 1.6 g/day Women = 1.1 g/day Pregnant = 1.4 g/day Lactating = 1.3 g/day *Assume that 10% of total omega-3 fatty acids come from EPA/DHA*	

	Selenium		Iron		Methylmercury		Dioxin/Dioxin-like Compounds	
Food Choice	# Data points	µg/3 oz[a,*]	# Data points	mg/3 oz[a,*]	# Data points	µg/3 oz[b,**]	# Data points	TEQ/3 oz[c,***]
Salmon	N/A	35.2	2	0.3	N/A	1	N/A	21
White (albacore) tuna	2	55.8	5	0.8	N/A	29	N/A	No data
Light tuna	45	68.3	30	1.3	N/A	10	N/A	1

Shrimp	58	33.7	N/A	2.6	N/A	4	N/A	4
Beef, 20% fat	72	18.3	36	2.1	N/A	0	N/A	20
Beef, 10% fat	72	18.4	36	2.3	N/A	0	N/A	10
Chicken[i]	20	23.5	16	0.9	N/A	0	N/A	2
Egg[i]	69	26.2	14	1	N/A	0	N/A	2
Point of Reference	RDA[2,f] Men and women = 55 ∝g/day Pregnant = 60 ∝g/day Lactating = 70 ∝g/day		RDA[3,f] Men = 8 mg/day Women = 18 mg/day Pregnant = 27 mg/day Lactating = 9 mg/day		Rfd[4,g] Men and women = 0.1 ∝g/kg/day		TDI[5,h] Men and women = 1–4 TEQ/kg/day	

NOTE: N/A means that the values are not available.

[a]For nutrient data: Salmon = Salmon, Atlantic, farmed, cooked; White tuna = Tuna, white, canned in water, drained; Light tuna = Tuna, light, canned in water, drained; Shrimp = Shrimp, cooked, moist heat; Beef, 20% fat = Beef, ground, 80% lean/20% fat, broiled; Beef 10% fat = Beef, ground, 90% lean/10% fat, broiled; Chicken = Chicken, breast, meat only, cooked, roasted; Egg = Egg, whole, cooked, hard-boiled.

[b]For methylmercury data: White tuna = Tuna (canned, albacore); Light tuna = Tuna (canned, light); Beef = Beef w/vegetables in sauce, from Chinese restaurant; Chicken = Chicken breast, roasted; Egg = Egg, boiled.

[c]TEQ = Toxicity Equivalency (see Chapter 4 for explanation); Because of different analytical methods, the dioxin/DLC data are averaged from 2001, 2002, and 2003. Ground beef represents lower-fat beef, chuck roast represents higher-fat beef, roasted chicken breast data was used for "chicken," and boiled egg data was used for "egg."

[d]EER = Estimated Energy Requirements. EER for men aged 19 years and older = 662 – (9.53 . age in years) + PA(15.91 . weight in kilograms + 539.6 . height in meters); reference man is 70 kg in weight, 1.77 m in height, PA of 1.11 (low active). EER for women aged 19 years and older = 354 – (6.91 . age in years) + PA(9.36 . weight in kilograms + 726 . height in meters); reference women is 57 kg in weight, 1.63 m in height, PA of 1.12 (low active).

[e]AI = Adequate Intake; the recommended average daily intake level that is assumed to be adequate for a group (or groups) of apparently healthy people, used when an RDA cannot be determined.

[f]RDA = Recommended Dietary Allowances; the average daily dietary nutrient intake level sufficient to meet the nutrient requirement of 97 to 98 percent of healthy individuals in a particular life stage and gender group.

[g]Rfd = Reference Dose; an estimate (with uncertainty spanning perhaps an order of magnitude) of daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime; for a 70 kg reference man the Rfd is 7 ∝g/day; for a 57 kg reference women the Rfd is 5.7 ∝g/day.

continued

TABLE 5-1 Continued

[h]TDI = Tolerable Daily Intake; represents an index for a contaminant similar to the Adequate Daily Intake, used for food additives. These limits are based on the assumption of an experimental threshold dose level below which no toxic effect is found in animal models and includes an additional uncertainty factor for extrapolation to humans. TEQ = Toxicity Equivalency.

[i]EPA/DHA levels in chicken and egg are based on existing published data; changes in the use of fishmeal in feed sources may have an impact on levels detected in the future.

SOURCES:
*USDA, 2005.
**Adapted from http://www.cfsan.fda.gov/ ~frf/sea-mehg.html; Carrington et al., 2004; Mahaffey, 2004; CFSAN, 2005b.
***Adapted from CFSAN, 2005a.
[1] IOM, 2002/2005.
[2] IOM, 2000.
[3] IOM, 2001.
[4] NRC, 2000.
[5] IOM, 2003.

TABLE 5-2 Data Available on Sampling of Selenium, EPA/DHA, and Mercury in Food

Food	Selenium[a]	EPA/DHA[a]	Methylmercury[b]
Salmon (Atlantic, farmed, cooked)	N/A*	2 samples	5 samples: 4 from 1992, 1 from 1993
Tuna (light, canned in water, drained)	45 samples	5 samples	2 samples from 1991–1992 (plus 131 samples for methylmercury from 2003–2004)
Shrimp	58 samples	11 samples	19 samples from 1991–1992, 1993, 1996 (plus 2 samples for methylmercury from 1993 and 1995)
Chicken[c]	20 samples (data over 20 years old); New data forthcoming show most nutrient levels comparable to earlier samples, but EPA/DHA levels as undetectable.		44 samples from 1990–1993 through 2003–2004

*N/A means that the values are not available.

SOURCES:
[a]Data from USDA Agriculture Handbook 8 (1976–1992) and its four supplements (1990–1993) as listed in USDA, 2005.
[b]CFSAN, 2006a.
[c]Personal communication, J.M. Holden, USDA-ARS-BHNRC-NDL, Beltsville, MD, March 30, 2006.

Nobmann and Lanier, 2001). Native Alaskans who switched from their traditional diet high in seafood products had few affordable healthful substitution foods from which to choose. When they decreased their seafood intake, they purchased more processed foods that were less nutrient-dense (such as manufactured snack products) and actually decreased the overall quality of their diets (see discussion Chapter 2, *American Indian/Alaska Native and First Nations Populations*).

Table 5-2 illustrates the available sampling data on nutrients and contaminants in food. The Agricultural Research Service (ARS) of the US Department of Agriculture (USDA) has begun updating its nutrient database through its National Food and Nutrient Analysis Program in collaboration with the National Institutes of Health (NIH). This ambitious project, which began in 1997, includes instituting a monitoring program for key foods and critical nutrients; conducting a thorough analysis of selected poultry products, restaurant foods, and items on FDA's list of the most commonly consumed fruits, vegetables, and seafood; and developing databases of foods of importance to ethnic subpopulations (Source: http://www.ars.usda.gov/Research/docs.htm?docid=9446).

In the committee's judgment, it is important to conduct substitution analyses of the potential impacts of changes in consumption despite the uncertainties about the underlying nutrient and contamination levels. These analyses are incorporated into the balancing of benefits and risks in the following discussion.

Part D: Balancing the Benefits and Risks to Arrive at Specific Guidance for Healthy Consumption

To complete the scientific analysis considering benefits and risks together, the committee developed the following consumption guidance for each of the four target population groups:

1. Females who are or may become pregnant or who are breast-feeding:
   a. May benefit from consuming seafood, especially those with relatively higher concentrations of EPA and DHA;
   b. A reasonable intake would be two 3-ounce (cooked) servings but can safely consume 12 ounces per week;
   c. Can consume up to 6 ounces of white (albacore) tuna per week;
   d. Should avoid large predatory fish such as shark, swordfish, tilefish, or king mackerel.
2. Children up to age 12:
   a. May benefit from consuming seafood, especially those with relatively higher concentrations of EPA and DHA;

b. A reasonable intake would be two 3-ounce (cooked), or age-appropriate, servings but can safely consume 12 ounces per week;
c. Can consume up to 6 ounces (or age-appropriate servings) of white (albacore) tuna per week;
d. Should avoid large predatory fish such as shark, swordfish, tile - fish, or king mackerel.

3. Adolescent males, adult males, and females who will not become pregnant:
   a. May reduce their risk for cardiovascular disease by consuming seafood regularly, e.g., two 3-ounce servings per week;
   b. Who consume more than two servings a week should choose a variety of types of seafood to reduce the risk for exposure to contaminants from a single source;
4. Adult males and females who are at risk of cardiovascular disease:
   a. May reduce their risk of cardiovascular disease by consuming seafood regularly, e.g., two 3-ounce servings per week;
   b. Although supporting evidence is limited, there may be additional benefits from including high-EPA/DHA seafood selections;
   c. Who consume more than two servings a week should choose a variety of types of seafood to reduce the risk for exposure to contaminants from a single source.

This information differs from the dietary guidance and advisories available from federal agencies and private organizations (see Chapter 2) in three important ways. First, the information combines benefit and risk information to yield coordinated statements. Second, the information comprehensively covers everyone in the population so that population groups are not left with uncertainties about which information applies to them. Third, while previous guidance has had tailored messages for people with a risk for cardiovascular disease (and to those with a history of such disease), the committee concludes that current scientific evidence suggests that the guidance for them is not materially different from that for the more general "adolescent males, adult males, and females who will not become pregnant" reflected above. For this reason the decision pathway that follows focuses on target populations 1–3 identified above. This suggested guidance should be reconsidered periodically as new data on risks and benefits associated with seafood consumption emerge.

The suggested guidance presented above is the endpoint of judgements about the important benefits and risks, as well as how they balance. The process of forming such guidance can be made more transparent with the use of tables that present the key considerations. Table 5-3 illustrates this

TABLE 5-3 Potential for Benefits and Risks Associated with Seafood Choices by Population Group

Seafood Choices for Females Who Are or May Become Pregnant and Those Who Are Breastfeeding	
Choice	**Consume locally caught freshwater fish (commercial and recreational catches) only after checking state advisories.**
Potential for Benefit	Might reduce food costs; continues family traditions.
Potential for Risk	Potential for increased MeHg, dioxin, and PCB exposure compared to other seafood selections. Risk for bacterial contamination will increase if consumed raw. Intake levels of iron will be lower than meat selections.
Choice	**May benefit from consuming seafood, especially those with relatively higher concentrations of EPA and DHA. A reasonable intake would be two 3-ounce (cooked) servings but can safely consume 12 ounces per week; should avoid large predatory fish such as shark, swordfish, tilefish, or king mackerel.**
Potential for Benefit	Seafood is a high-quality low-fat protein source. Intake levels of saturated fat will likely decrease compared to meat selections. Intake levels of EPA/DHA will increase compared to meat and "nonfatty" seafood selections. Intake of selenium may increase compared with beef, pork, and poultry selections.
Potential for Risk	Available data suggest levels of MeHg are not associated with adverse health effects if consumption is limited to no more than four 3-ounce servings per week. Potential risk from exposure to dioxins and PCBs is similar to meat selections. Risk for bacterial contamination will increase if raw seafood is consumed. Intake levels of iron will be lower than meat selections.
Choice	**Can consume up to 6 ounces of white (albacore) tuna per week.**
Potential for Benefit	Seafood is a high-quality low-fat protein source. Intake levels of saturated fat will likely decrease compared to meat selections. Intake levels of EPA/DHA will increase compared to meat and leaner seafood selections. Intake of selenium may increase compared with beef, pork, and poultry selections.
Potential for Risk	Available data suggest levels of MeHg are not associated with adverse health effects if consumption is limited to 6 ounces per week. Potential risk from exposure to dioxins and PCBs is similar to meat selections. Risk for bacterial contamination will increase if raw seafood is consumed. Intake levels of iron will be lower than meat selections.
Seafood Choices for Children up to Age 12	
Choice	**May benefit from consuming seafood, especially those with relatively higher concentrations of EPA and DHA.**
Potential for Benefit	Decreased caloric intake from total and saturated fats and increased intake of selenium compared with beef, pork, and poultry selections. Intake levels of EPA/DHA will increase compared to meat and lean seafood selections.
Potential for Risk	Available data suggests levels of MeHg in high-EPA and -DHA seafood are not associated with adverse health effects at recommended consumption levels. Potential risk from exposure to dioxins and PCBs is similar to meat selections. Decreased intake of iron compared to meat selections. Risk for bacterial contamination will increase if raw seafood is consumed.

continued

TABLE 5-3 Continued

Choice	**A reasonable intake would be two 3-ounce (cooked) or age-appropriate servings but they can safely consume 12 ounces per week.**
Potential for Benefit	Intake levels of EPA/DHA will increase compared to meat and lean seafood selections. Decreased caloric intake from total and saturated fats compared with beef, pork, and poultry selections, but increased compared to lean seafood selections. Increased intake of selenium compared to meat selections.
Potential for Risk	Potential for greater exposure to dioxins and PCBs compared with lean seafood. Decreased intake of iron compared to meat selections.
Choice	**Should avoid large predatory fish such as shark, swordfish, tilefish, or king mackerel.**
Potential for Benefit	Available data suggests reduced exposure to MeHg. No anticipated impact on exposure to POPs.
Potential for Risk	Intake levels of EPA/DHA and selenium will be lower if meat is selected as a substitute.
Choice	**Can consume up to 6 ounces of white (albacore) tuna per week.**
Potential for Benefit	Seafood is a high-quality low-fat protein source. Intake levels of saturated fat will likely decrease compared to meat selections. Intake levels of EPA/DHA will increase compared to meat and leaner seafood selections. Intake of selenium may increase compared with beef, pork, and poultry selections.
Potential for Risk	Available data suggest levels of MeHg are not associated with adverse health effects if consumption is limited to two 3-ounce servings per week. Potential risk from exposure to dioxins and PCBs is similar to meat selections. Risk for bacterial contamination will increase if raw seafood is consumed. Intake levels of iron will be lower than meat selections.
Seafood Choices for Adolescent Males, Adult Males, and Females Who Will Not Become Pregnant	
Choice	**Consume seafood regularly, e.g., two 3-ounce servings per week; if more are consumed, then insure a variety of choices are made to reduce exposure to contaminants.**
Potential for Benefit	Decreased caloric intake from total and saturated fats and increased intake of selenium compared with beef, pork, and poultry selections. Intake levels of EPA/DHA will increase compared to meat selections if high EPA/DHA seafood is selected.
Potential for Risk	Available data suggest levels of MeHg, dioxins, and PCB exposure will likely be within exposure guidelines regardless of type of seafood selected. The potential for exposure to contaminants is increased if locally caught seafood is consumed without regard to local advisories. Increased risk for exposure to infectious microorganisms if raw seafood is consumed. Decreased intake of iron compared to meat selections.

more detailed background approach to the design of guidance intended for the four target populations.

A decision tree or other decision representation is another way of depicting the consumption guidance listed above. This kind of diagram highlights the variables that group consumers into specific target populations who face different benefits and risks and who should receive tailored advice. In the committee's judgment, the variables that distinguish between target populations facing different benefit-risk balances, based on existing evidence, are age, gender, and pregnant or could become pregnant, or breastfeeding. A fourth distinguishing variable explored by the committee was risk of cardiovascular disease. However, as noted above, the committee believes the evidence is insufficient to warrant separate guidance to this group beyond that which would be offered based on age, gender, and pregnancy or breastfeeding status. These three variables, as they apply to the target population groups, are arrayed in a decision pathway, shown in Figure 5-2, that illustrates the committee's final analysis of the balance between benefits and risks associated with seafood consumption.

Acknowledging Limitations of the Benefit-Risk Analysis

The committee believes that it is fundamentally important to acknowledge that benefit-risk analysis as conducted here will always have limitations related to the availability of data on and evaluation of benefits and risks. For example, here the committee relied on data that contain a variety of uncertainties. In the case of seafood consumption, the potential for an adverse health effect from exposure to a contaminant is presumed to depend upon, among other things, differences in prior exposure levels as well as differences in sensitivity to toxicants among individuals. Likewise, persons may receive variable benefits, including no benefit, from nutrients that are found in higher concentrations in seafood than in most other foods, i.e., EPA/DHA and selenium. Those already at low risk for cardiovascular disease, for example, may see little cardiovascular benefit from seafood consumption. Furthermore, it is difficult to obtain information regarding when sampling occurred, the number of samples taken, and the methodology used to identify and quantitate specific nutrients over time, resulting in uncertainty about the variability of nutrient levels in seafood. Finally, no two samples of seafood, either from the same species or from different tissues in the same seafood will contain the same level of either nutrients or contaminants.

In the committee's judgment, these uncertainties may reduce the applicability of the guidance to a specific person, but the general guidance for safe seafood consumption applies to most persons in a category. The

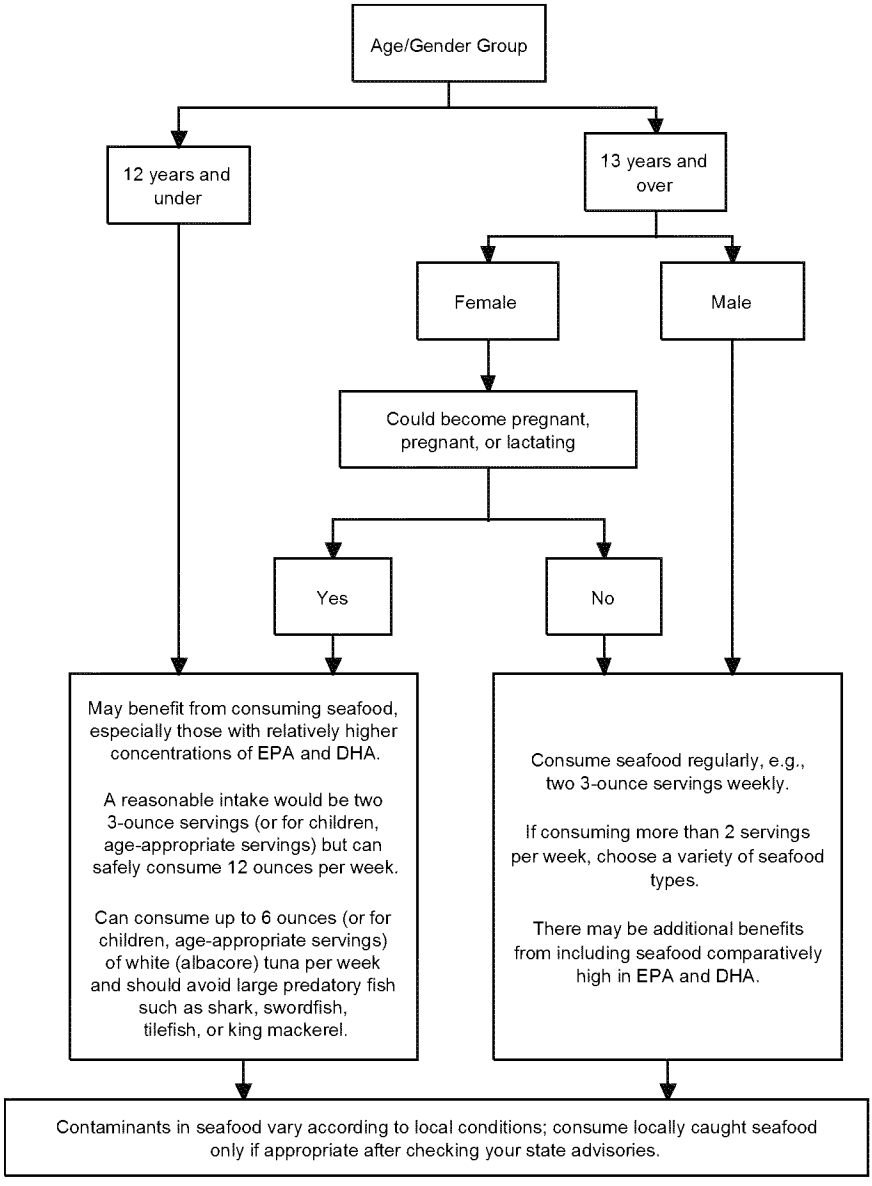

FIGURE 5-2 A decision pathway or representation of the balance between benefits and risks associated with seafood consumption. This diagram highlights the variables that group consumers into specific target populations who should receive tailored advice. Specific details about consumer advice are discussed in Chapter 7.

following points illustrate the variables that influence what can be generally applicable:

- Concentrations of contaminants in seafood are known to be influenced by factors such as location of harvest, seasonal variations, size, and species. General guidance to consumers must be based on available data for average levels of potential contaminants in type or species of seafood. Sparse data on adverse health effects associated with some contaminants make it difficult to estimate the variability of specific contaminant levels in seafood, as well as levels of EPA and DHA.
- Levels of EPA and DHA in seafood depend upon the fatty acid content of the type of seafood consumed, the source of fat in feed for farmed fish, and serving size. Sparse data make it difficult to determine variability in the EPA and DHA content. As more seafood is produced by aquaculture rather than wild-caught, EPA and DHA levels within species could change.
- There is considerable uncertainty about the concentration of contaminants that present a health risk. Methylmercury exposure levels that pose a risk were established for the most vulnerable members of the population, i.e., the fetus, infant, and young child. However, methylmercury exposure levels that pose a risk for adverse health effects for other population categories listed above are unknown. Similarly, exposure limitations for persistant organic pollutants, dioxins and dioxin-like compounds, and PCBs are unclear.
- Methylmercury intake exposures that are used to indicate a potential for risk for the fetus, infant, and young child are adjusted (as noted in Chapter 4) to make them more conservative than levels of observed risk.

These uncertainties mean that guidance to individual consumers can, at best, present the broad trade-offs of benefits and risks associated with seafood selections and consumption patterns, and inform consumers of the inherent uncertainties therein. The committee is aware that considerations other than health benefits or risks also may influence consumers' choice of seafood. These include environmental concerns about aquaculture and the sustainability of wild seafood stocks. These considerations are beyond the charge to the committee and are not included in the decision pathway.

FINDINGS

1. Relatively few studies have attempted to simultaneously assess both the health benefits and the risks associated with seafood consumption. However, there is emerging evidence of the trade-offs between the benefits

and risks associated with seafood consumption for health endpoints such as infant development and cardiovascular disease.

2. Given the uncertainty in the underlying exposure data and evolving health impacts, there is no summary metric that can adequately capture the complexity of seafood choices to balance benefits and risks for purposes of providing guidance to consumers. An expert judgement technique can be used to consider benefits and risks together, to yield specific suggested consumption advice.

3. Developing guidance on seafood consumption requires the development of a benefit-risk analysis that identifies the magnitude of benefits and risks associated with different types of consumption, identifies which are important enough to be included in the balancing process, evaluates changes in benefits and risks associated with changes in consumption patterns, and balances the benefits and risks to arrive at specific guidance for healthy consumption for the population as a whole or, if appropriate, for specific target populations.

4. Current evidence suggests that important benefits and risks to be considered in benefit-risk analysis vary across the following target populations: (1) females who are or may become pregnant and those who are breastfeeding; (2) children up to age 12; and (3) adolescent and adult males, and females who will not become pregnant. The committee did not find evidence that adult males and females who are at risk of cardiovascular disease differ from group 3 in terms of potential benefits and risks.

5. The impact of substituting selected species of seafood for other animal protein sources can result in increased consumption of EPA/DHA and selenium; however, impacts on saturated fats and energy intakes vary depending on the seafood selected.

6. The impact of substituting selected species of seafood for other animal protein sources on exposure to environmental toxicants other than methylmercury is uncertain due to inadequate supporting evidence.

7. Considering benefits and risks together yields specific suggested consumption guidance for the three targeted populations enumerated in Finding 4 above.

8. Guidance should be reconsidered periodically, and on an ongoing basis, as new data on both risks and benefits associated with seafood consumption emerge.

CONCLUSIONS

Combining expertise from the disparate relevant disciplines to consider benefits and risks simultaneously is an essential step to producing a comprehensive benefit-risk balancing analysis. An organization of experts is needed among appropriate federal agencies to oversee and manage coordinated

benefit-risk judgments and to implement a coordinated research effort to generate the data needed by agencies to issue timely, accurate, and continuously updated advice to consumers, including target populations.

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6

Understanding Consumer Decision Making as the Basis for the Design of Consumer Guidance

Chapter 5 outlined the three steps the committee deemed necessary to designing guidance to consumers about balancing benefits and risks in making seafood consumption decisions (see Box 5-1): scientific assessment and analysis of the benefits and risks; analysis of the consumer's decision making context; and production and evaluation of the guidance. Chapter 5 then detailed Step One: the evidence base for the information to include in the guidance (or what the consumer needs to know to make an informed decision). This chapter presents an approach to Step Two: developing an understanding of how consumers make seafood choices and the informational environment in which they do so. This environment includes both what information the consumer has access to and what the consumer needs or wants to know. Included in this chapter is an overview of the types of information that are currently available and evidence of the degree to which consumer choice has been influenced by it. The chapter then discusses reasons why consumer guidance may have weak or unintended impacts on consumer choice and what must be understood about the consumer decision-making context in order to design effective guidance.

INTRODUCTION

As noted in the previous chapters, there is a wide variety of guidance on seafood consumption currently available to consumers. Based on their analysis of nutritional benefits, some governmental agencies and nongovernmental organizations (NGOs) have recommended that most Americans consume two 3-ounce (cooked) servings of seafood weekly, with one of these

being a fatty fish (see Chapter 1). Other guidance cautions some consumers against specific types of seafood due to health risks. As shown in preceding chapters, different populations have different benefit-risk profiles, and guidance to consumers should be tailored to reflect this.

Receiving new information, such as dietary guidance, does not automatically lead consumers to change their food consumption patterns. Food choice is influenced by a complex informational environment that also includes labeling, point-of-purchase information, commercial advertising and promotion, and Web-based health information. Specific guidance may have a limited impact, although evidence suggests that this varies significantly and in general is not well measured or understood; current advice may create unintended consequences in consumer choices. A better understanding of the sociocultural, environmental, economic, and other individual factors that influence consumer choice is necessary for the design of effective consumer guidance, especially where the intent is to communicate balancing of benefits and risks associated with its consumption.

FOOD CHOICE BEHAVIOR

Food Consumption Decisions

Identification of Factors Influencing Food Consumption Decisions

Studies of food choice behavior have identified both individual and environmental factors that influence the complex process of decision making (Lutz et al., 1995; Galef, 1996; Drewnowski, 1997; Nestle et al., 1998; Booth et al., 2001; Wetter et al., 2001; Bisogni et al., 2002; Devine, 2005; Raine, 2005; Shepard, 2005). Factors influencing seafood consumption choices are similar to those for other foods (e.g., taste, convenience, or ease of preparation) (Gempesaw et al., 1995).

Individual Influences When consumers are asked what is most important when choosing food, taste is the most likely response (Drewnowski, 1997). However, a variety of other individual factors (e.g., habit) (Honkanen et al., 2005) also influence consumer decisions about consumption or avoidance of specific foods (Lutz et al., 1995; Galef, 1996; Drewnowski, 1997; Nestle et al., 1998; Booth et al., 2001; Bisogni et al., 2002; Devine, 2005). For example, some people will override taste to select foods to benefit their health (Stewart-Knox et al., 2005). The choice for healthfulness is further affected by choice of preparation method and food consumption outside the home (Blisard et al., 2002). For other consumers, issues of convenience, availability, and cost may play greater roles than concerns about health. What is unknown is the degree to which these factors determine final food selection.

Environmental Influences Taste is influenced by genetics (Birch, 1999; Mennella et al., 2005a) and exposure throughout life (Birch, 1998; Birch and Fisher, 1998; Mennella et al., 2005b). Other environmental factors that influence seafood choices include accessibility of seafood as a subsistence food (Burger et al., 1999b), cultural tradition (Willows, 2005), price of seafood and of seafood substitutes (Hanson et al., 1995), and health and nutrition concerns (Gempesaw et al., 1995; Trondsen et al., 2003). For example, some consumers make seafood choices based on concerns about environmental impact (see Monterey Bay Aquarium's Seafood Watch [http://www.mbayaq.org/cr/seafoodwatch.asp], production methods, or geographical origin (Figure 6-1).

An individual's food choices are made based on their history but are influenced by a changing environment over time (Devine, 2005; Wethington, 2005). While most patterns of choice (trajectories) are stable throughout life, significant societal and personal events, as well as relationships, influence these patterns. The timing of these events may greatly influence subsequent food choices. In response to these external events and internal changes, individuals may or may not choose to adopt strategies to improve their health and change their lifestyle behaviors. Using the pregnant woman as an example (see Appendix C-1), one can examine the complexity of food choice using the Life Course Perspective framework (see Appendix C-2).

Economic Considerations Associated with Food Choice Behavior

Economic considerations may also influence consumer food choice behavior. Evidence suggests that seafood is a good substitute for other protein foods (Salvanes and DeVoretz, 1997; Huang and Lin, 2000). US consumers have the lowest income elasticity of demand (the percentage change in demand for a 1 percent change in income) for the overall category of "food, beverages, and tobacco" of 114 countries, based on an analysis of 1996 data (Seale et al., 2003). This indicates that, on average, their food expenditures are not very sensitive to income changes. For the subcategory of fish, Seale et al. also found the US expenditure elasticity (the percentage change in demand for a 1 percent change in expenditures on a category) lowest among the 114 countries studied. Similarly, US consumers had the lowest own-price elasticities of demand (the percentage change in demand for a one percent change in price) for fish among the countries studied.

More detailed analysis within the United States suggests further income and price considerations that may influence how consumers implement guidance on seafood choices. For example, Huang and Lin (2000) used 1987–1988 National Food Consumption Survey data to estimate expenditure and own-price elasticities adjusting for changes in the quality of the foods consumed across different income groups. Expenditure and own-

FIGURE 6-1 Framework for factors influencing healthy eating and physical activity behaviors. The schema depicts a psychobiological core composed of genetic, psychological (e.g., self-esteem, body image, disagreement with personal vulnerability or gain from choices), and physiological influences (e.g., gender, age, health status, responses to specific components in food, hunger, and satiety). This core is embedded within a social-cultural context (e.g., families and friends, religion and tradition, economic and other resources, awareness and knowledge of the implications of choice), and impact of consumer advertising and information that can either enhance or inhibit healthful food choices and other lifestyle behaviors. In addition to these individual characteristics, the larger environment (e.g., neighborhoods, communities, schools, worksites) along with policy decisions (e.g., health advisories and guidance; economic and political priorities) greatly influence the individual's food decisions (Wetter et al., 2001; Raine, 2005). Food availability, convenience, cost considerations, and food subsidies also are included in the environmental layers of influence. SOURCE: Adapted, with permission, from Booth et al. (2001). Copyright 2001 by International Life Sciences Institute.

price elasticities vary between low-, medium-, and high-income consumers, although the extent differs between food products (Yen and Huang, 1996; Huang and Lin, 2000). They also conclude that the quality of items chosen by consumers (e.g., different cuts of beef within the beef subcategory) is clearly linked to income level. Similarly, an analysis of household expenditures on fruits and vegetables shows significant differences in expenditure per capita between low-income and higher-income households, as well as differences in the income elasticity of demand (Blisard et al., 2004). These results suggest that population averages may conceal significant differences between income groups in terms of their demand responses to income, expenditure, and price changes.

Impact of Factors Influencing Food Consumption Decisions

In general, when consumers are presented with new information, e.g., balancing health benefits with risks of seafood choices, food choice behavior theories suggest that they will interpret and respond to this information in light of their existing beliefs, attitudes, and habits, and will be influenced by situational factors as much as or more than by the content of the information.

For example, in a long-term, randomized controlled study involving advice to men with angina to eat more fish and vegetables, small increases in fish consumption were observed (Ness et al., 2004), but this did not appear to improve survival (Ness et al., 2002). Even with carefully planned prospective studies of the consequences of giving advice, it can be difficult to discern the effect of advice, due to potentially confounding influences (see also *Impact of State Advisories* below). Advice provided publicly may be focused on by the media, reinforced or contradicted by other policy measures, or obscured by other news (Kasperson et al., 2003).

As Ness et al. (2004) illustrated, knowledge does not necessarily lead to the intended changes in consumption patterns. In addition, once a decision is made, many processes are involved in implementing and sustaining a change (Appendix C-3). Among the many theories used to explain both food choice behavior (and its subsequent impact on health) and behavior change (Achterberg and Trenker, 1990), a few are highlighted in Appendix C-2.

The Current Information Environment Influencing Seafood Choices

Consumers have access to several different types of communication that form a complex information environment in which they make decisions. Each of these plays a role in their decisions, either as a source of information or as a facilitator of choice.

A striking aspect of the information available to consumers is that it

is not systematically coordinated. This lack of coordination would not be unexpected between public agencies and private organizations, or between groups who may have different interpretations of the evidence about what is a healthful eating pattern as well as different goals in giving advice. However, even within the federal government, guidance to consumers has not been systematically coordinated, either on a benefit-by-benefit or risk-by-risk basis, as illustrated by the differences between recommendations on portion sizes and frequency of consumption (see Table 1-2 and Appendix Table B-3).

Elements of the information environment which government agencies can control include labels, other point-of-purchase information in the retail environment, and restaurant and fast-food outlet menus.

Labels and Other Point-of-Purchase Information

Ingredient and Nutrition Labeling Ingredient labeling gives consumers content information about packaged seafood products. In some cases, regulation also restricts use of terms in identifying products. For example, only albacore tuna can be labeled as "white tuna," while "chunk light tuna" may include several species of tuna.

Nutrition labeling in the form of the Nutrition Facts panel is mandatory in the United States for packaged products, while the use of voluntary nutrient content and health claims is also regulated. Fresh foods are exempt from mandatory labeling. In 1992, the US Food and Drug Administration (FDA) issued guidelines for a voluntary point-of-purchase nutrition information program for fresh produce and raw fish. The guidelines are scheduled to be revised in 2006 to make them more consistent with mandatory nutrition labeling requirements (Personal communication, K. Carson, Food and Drug Administration, April 1, 2006). To meet the guidelines, a retailer must include the following nutrition information on the point-of-purchase label for seafood that is among the 20 types most commonly eaten in the US: seafood type; serving size; calories per serving; protein, carbohydrate, total fat, cholesterol, and sodium content per serving; and percent of the US Recommended Dietary Allowances (RDA) for iron, calcium, and vitamins A and C per serving (FDA, 2004a). A serving is defined as 3 ounces or 85 grams cooked weight, without added fat or seasoning.

Qualified Health Claims Labeling While the standard Nutrition Facts format informs consumers about several nutrition characteristics of seafood products, it does not list omega-3 fatty acid content. In 2004, the FDA announced the availability of a qualified health claim for reduced risk of coronary heart disease on conventional foods that contain eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Qualified health claims on

foods must be supported by scientific evidence as outlined in the guidance document, *Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements* (CFSAN, 2003). In addition, the FDA is conducting further consumer studies to make sure the language used in claims is well understood by consumers (FDA, 2004b).

In the interim period, the FDA will prioritize health claims for review based on the potential significance of the product's health impact on a serious or life-threatening illness, and the strength of evidence in support of the claim. The health claims that will be evaluated first include the benefits of eating foods high in omega-3 fatty acids, including certain fatty fish like ocean salmon, tuna, and mackerel, for reducing the risk of heart disease.

Country of Origin and Other Labeling The 2002 Supplemental Appropriations Act amended the Agricultural Marketing Act of 1946 to require retailers to inform consumers of the country of origin of wild and farm-raised fish and shellfish. This information can be conveyed by label, stamp, mark, placard, or other clear and visible sign on the product, package, display, holding unit, or bin containing the seafood at the final point of consumption. Food service establishments are exempt, as are processed products.

Box 6-1 describes an unresolved issue over which governmental sector has the authority to control the consumer's access to certain information

BOX 6-1
Challenge to California's Proposition 65

In 2005, the Food and Drug Administration claimed that California's action was a violation of federal law. On March 8, 2006, the House passed HR 4167, the *National Uniformity for Food Act,* which amends the Federal Food, Drug, and Cosmetic Act to "provide for uniform food safety warning notification requirements" and to supersede state legislation and practices on food-warning labels, including Proposition 65. At the writing of this report, the Act had not passed the Senate. An amendment to the Act included a clause to exclude mercury warnings: "Nothing in this Act or the amendments made by this Act shall have any effect upon a State law, regulation, proposition or other action that establishes a notification requirement regarding the presence or potential effects of mercury in fish and shellfish."

SOURCE: http://www.govtrack.us/data/us/bills.text/109/h/h4167.pdf.

regarding food. In 2004, the Attorney General of California joined a lawsuit filed by the Public Media Center, a nonprofit media and consumer advocacy agency in San Francisco, against the nation's three largest canned tuna companies to enforce Proposition 65, California's 1986 law requiring warnings about exposure to contaminants, such as methylmercury.

Restaurant and Fast-Food Menu Information The away-from-home sector is exempt from nutritional and country of origin labeling requirements. Further, many restaurants do not identify seafood products such as breaded fish sandwiches by species. Some of this information is provided voluntarily, and this may increase with consumer demand for specific types of seafood.

In April 2003, the Attorney General of California filed suit against major restaurant chains in the state for violating Proposition 65 requirements to inform consumers of potential exposure to "substances known by the state to cause cancer or reproductive toxicity" by failing to post "clear and reasonable" consumer warnings about exposure to mercury in seafood (i.e., shark, swordfish, and tuna). The suit was settled in early 2005, when most of the restaurants agreed to put up warnings about the risks from mercury in seafood near the front door, hostess desk or reception area, or entry or waiting area (California Office of the Attorney General, [http://ag.ca.gov/newsalerts/2005/05-011.htm]). The information provided in this sector remains largely unregulated. The outcome of the lawsuit concluded that labeling under Proposition 65 was preempted for mercury in tuna, although the decision was specific to the circumstances in the case. All applications of Proposition 65 to food were not preempted by the decision. Moreover, this decision was by a state judge and specific to Proposition 65 and California—not other laws or other states.

Regulated Point-of-Purchase Information Retailers may place nutrition information on individual food wrappers or on stickers affixed to the outside of the food. Compliance with point-of-purchase guidelines is checked by biennial surveys of 2,000 food stores that sell raw produce or fish and the results are reported to Congress. Additionally, every 2 years the FDA publishes, in the Federal Register, revised nutrition labeling data for the 20 most frequently consumed raw fruits, vegetables, and fish.

Recent research suggests that the amount of information available on fresh seafood products in retail settings varies markedly, with counter staff frequently unable to provide additional information (Burger et al., 2004). In addition to the quantity and types of information available to consumers, the accuracy of information should also be considered. Limited tests indicate that seafood products may be misrepresented—for example, sold as wild when they are in fact farmed (Is Our Fish Fit to Eat, 1992; Burros, 2005).

Advertising and Promotion

Advertising and promotion may include nonregulated point-of-purchase information, which can be displayed on placards, shelf tags, or in pamphlets or brochures. In addition to regulated labeling and point-of-purchase information, several types of retail information are available to consumers making food choices. For processed foods, packaging information includes the brand, product name, and unregulated product claims and other information. It is estimated that $7.3 billion was spent on advertising food in 1999 (Story and French, 2004).

As well, several other forms of point-of-purchase (e.g., signage, brochures) and other forms of information (e.g., websites) may be provided. Other means to convey this information to consumers may include live demonstrations, computer booths, or recorded presentations as adjuncts to the printed information.

Web-Based health Information

Interactive Health Communication Much of the rapidly rising use of the Internet is devoted to seeking health information: four out of five Internet users (95 million Americans) have Internet access to look for health-related information; 59 percent of female users have used the Internet to look for information on nutrition (Fox, 2005). The promise of eHealth and, in particular, interactive health communication (IHC) (Eng et al., 1999; Eng and Gustafson, 1999; Wyatt and Sullivan, 2005), has captured the attention of health communicators, in part due to the ability to target and tailor communications, disseminate them rapidly, and engage the audience in an exchange of information, rather than a one-way message delivery (Gustafson et al., 1999); compared with Griffiths et al., 2006. Evaluation of IHC, which falls under the category of eHealth, remains challenging (Eysenbach and Kummervold, 2005). While ethical issues such as unequal access to the Internet and maintaining confidentiality of information pose challenges, IHC has become an important tool for health communicators.

Online Seafood Information and Advocacy There are currently several examples of online seafood consumption information and advocacy available, as illustrated in Table 6-1. For example, Oceans Alive, a nongovernmental organization (Environmental Defense Network), offers "Buying Guide: Becoming a Smarter Seafood Shopper," on its website (http://www.oceansalive.org/eat.cfm). Other sites offer nutrition information about seafood; however, a cursory glance suggests that some sites may not be updated frequently, and so may provide out-of-date nutritional and other guidance. Updating is likely to be a challenge for any interactive guidance

TABLE 6-1 A Sampling of Online Consumer Information and Advocacy Sites Which Include Mercury Calculators

Website	Organization	Type of Organization/Project	Input
http://www.ewg.org/issues/mercury/20031209/calculator.php	Environmental Working Group (EWG)	Public health and environmental action organization	Consumer's weight (lbs) Consumer's gender
http://www.fishscam.com/mercuryCalculator.cfm	FishScam.com	A project of the Center for Consumer Freedom A nonprofit organization supported by restaurants, food companies, and individuals, created by Berman & Co., a public affairs firm which has represented various animal production industries	Consumer's weight (lbs) Fish of choice (dropdown menu provided)
http://gotmercury.org/english/advanced.htm	Got Mercury?	A project of Turtle Island Restoration Network Public education and campaign to reduce exposure to methylmercury from seafood	Consumer's weight (lbs) Type of fish consumer has eaten in a week Amount (oz) of up to three different fish consumer has eaten in a week (dropdown menu provided)

Output	Notes/Quoted Extracts
Amount of canned albacore and canned light tuna you can safely eat (g/kg of weight/day) Based on FDA's health standard (i.e., safe dose)	Assumes that you do not eat any other seafood. Assumes that every can of tuna has an average amount of mercury. The FDA recommends up to 12 ounces a week of a variety of fish. If you eat other seafood, the amount of tuna that you can eat safely will be less than calculated here. EWG recommends that women of childbearing age and children under 5 not eat albacore tuna at all, because a significant portion of albacore tuna has very high mercury levels. People eating this tuna will exceed safe exposure levels by a wide margin.
Amount (oz) of each fish you can eat weekly without introducing new health risks from mercury Based on the US EPA's Reference Dose Links the US EPA's "Reference Dose" and the theoretical harm threshold (a number ten times greater, called the "Benchmark Dose lower limit") to the Glossary section of this website	The EPA knows the level of exposure that represents a hypothetical risk, but it adjusts it by a factor of 10 in order to arrive at its "Reference Dose." It's this smaller, hyper-cautionary number that environmental groups use to scare Americans into thinking that tiny amounts of mercury in fish represent a real health hazard. According to fishy math from EWG and SeaWeb, for instance, your health is in grave danger if you consume just 12 ounces of tuna (canned chunk light) in a given week. This trickery is responsible for a great deal of needless fear. And food-scare groups ignore the fact that health risks from mercury take an entire lifetime to accumulate. It's simply not possible to get mercury poisoning from eating a week's worth of any commercially available fish.
Mercury exposure (% of EPA limit) Based on the US EPA's reference dose	Please be aware that these values are averages. The concentration of mercury in seafood can be significantly higher or lower than what is represented here. As a precautionary approach, we recommend that women (especially of childbearing age) avoid seafood species that contain higher average levels of mercury. Mercury information for many shellfish species is currently unavailable. Data source: FDA website (http://www.cfsan.fda.gov/~frf/sea-mehg.html). Two exceptions are the troll-caught albacore data which come from an Oregon State University study and canned albacore data, which come from an FDA dataset that is not yet published on its site.

continued

TABLE 6-1 Continued

Website	Organization	Type of Organization/Project	Input
http://www.nrdc.org/health/effects/mercury/index.asp	Natural Resources Defense Council (NRDC)	An environmental action organization	Consumer's weight (lbs) Types of fish consumer has eaten in the last month Number of portions consumer has eaten of each fish Portion sizes for each fish meal
http://www.oceanconservancy.org/site/PageServer?pagename=mercuryCalculator	The Ocean Conservancy	A research, education, advocacy organization advocating for the oceans	Consumer's weight (lbs) Average number of 6 oz servings/week of different seafood types (list provided)

tool. Information on the nutrient content of foods, including seafood, can be obtained through the USDA nutrient database (USDA, 2005b; Source: http://www.nal.usda.gov/fnic/foodcomp/Data/SR18/sr18.html) (see also Chapter 5, Table 5-2 and discussion).

Currently, much of the interactive seafood consumption information available on the Web consists of mercury intake calculators that may include tailoring by the decision-maker's weight, sometimes gender, and the type and amount of seafood consumed (Table 6-1). In addition, the computer - ized nutritional information approach has been successful and shown some promise in other domains (Lancaster and Stead, 2002; Eng et al., 1999). Computerized nutrition information in the form of menu planning has been ongoing since the mid-1960s (Balintfy, 1964; Eckstein, 1967) and is still being developed (Bouwman et al., 2005).

Northern Contaminants Program

The Northern Contaminants Program (NCP) is funded by a commit - ment of one million dollars a year from the Canadian government and managed by aboriginal communities. The aim of the program is to reduce

Output	Notes/Quoted Extracts
Estimated level of blood mercury (∝g/L), level of blood mercury that the US EPA considers safe Based on the US EPA's Reference Dose Link to FDA's 2003 data on levels of mercury in 17 types of fish	Because the numbers used in the mercury calculator are averages, the fish you eat may contain mercury at levels significantly higher or lower than the numbers used in this calculator. The results of the calculator are only an estimate of the possible level of mercury in your blood and should not be considered definitive. The estimate does not predict any risk to you or your family. If you are concerned about the calculator's results or wish to get a more accurate reading through a blood mercury test, you should talk to your doctor.
Total mg/kg mercury per week Based on the US EPA's Reference Dose	If your results are less than 0.7 below, your mercury levels are likely within EPA's recommended range. If your results exceed 0.7, your levels may be higher than EPA recommends. Data source: "Mercury Levels in Commercial Fish & Shellfish," by FDA and EPA (http://vm.cfsan.fda.gov/~frf/sea-mehg.html)

and eliminate some of the contaminants reaching the Arctic, and to inform and educate Northerners about the issue of contaminants. Relevant to this report is the work that is being done to inform and educate Northerner Dwellers about the issue and how to manage their diet around existing and emerging contaminant issues.

The initial response of Northern aboriginal communities to information on contaminants in aquatic food was a dramatic switch away from eating "country foods." In a region where there are few readily available and affordable nutritional alternatives and 56 percent of the population is "food insecure," this exposed the population to a greater risk from poor nutrition than that posed by the contaminants. Communication about contaminants also affected the social structure of the region as it had a negative impact on the practice of sharing food, due to concerns that hunters might be poisoning friends and family. There was also a negative impact on the efforts of health workers to encourage breastfeeding in the region.

Under the NCP, any contaminant information has to be filtered through a community committee made up of representatives from the aboriginal and Inuit organizations, and health and wildlife workers. This committee is responsible for taking the messages that scientists may develop, and turning

them into something that can be presented to and discussed with the communities. This communication process has enabled the scientific assessments to be merged into different communication practices that result in better public perception and understanding.

In the Inuit culture, each community has its own particular system of knowledge and way of understanding, and the NCP has adapted communication activities to these systems. Among the targeted and tailored communications activities are school curriculums for children, posters, little newsletters, and fact sheets. Radio, video shows, and a whole myriad of different technologies are used to communicate these messages.

Most of these communications relate to benefits—country foods are good for you and important for good nutrition. Little is said about contaminants because the community had established that people really do not care about bioaccumulation or PCBs. They want to know if their food is good to eat. The community has told the scientists that contaminant messages cannot just be "dumped" on communities. Information has to be put into a context of an overall health and nutrition message. The NCP is delivering these tailored health and nutrition messages, targeted to specific audiences such as youth and pregnant or nursing women through a community-based stakeholder program (Personal communication, E. Loring, Inuit Tapiriit Kanatami, August 3, 2006; http://www.ainc-inac.gc.ca/ncp/).

Summary

In summary, guidance to consumers regarding the benefits and risks of seafood consumption may inform individual choices about which types of seafood and how much to consume. The design of guidance should consider the context of other product information, particularly labeling, available to consumers to facilitate choice. These other information sources affect choice as well as influence how effectively consumers can implement their decisions once they are made. This distinction is important. For example, labels provide information that consumers use to decide which products to buy just as consumer guidance does. But they also facilitate choices that have already been made. If, following guidance, consumers decide to add a particular type of seafood from a specific region to their diets, will they be able to effectively identify this product in a retail store? Do restaurant and fast-food outlet menus give sufficient information for consumers to implement their choices made on the basis of guidance?

IMPACT OF INFORMATION ON CONSUMER DECISION MAKING

Although it is difficult to attribute observed behavior changes to specific advice, like national and local fish advisories, awareness of advisories

suggests that they contribute to avoidance. For example, shifts away from traditional (country) foods, much of which is seafood, due to concerns that include mercury and other pollutants, have resulted in striking increases in anemia, dental caries, obesity, heart disease, and diabetes among the native populations of Northern Canada (Willows, 2005). Another example of an unanticipated effect of risk information is the Alar controversy of 1989 (Marshall, 1991), which effectively stigmatized apple consumption until Alar was pulled from the market later that year.

As these examples show, reactions to risk information can prevail over, and change, preferences and markets; consumer information may appear to have little direct influence, but it can have substantial unanticipated consequences. The combination of responses to and changing understanding of food consumption choice consequences can amplify the effects of risk information, which can be further amplified by the media, government, and other parties (Kasperson et al., 2003). Providing information about risks in the absence of benefit information is likely to produce negative responses (Finucane et al., 2003; Slovic et al., 2004), compounding the tendency to omit consideration of factors that are not mentioned explicitly (Fischhoff et al., 1978).

Seafood choices, like all consumption choices, may entail value trade-offs (see Chapter 7). Well-designed guidance and information can simplify making such trade-offs for consumers by:

- Taking into account consumers' own decision objectives;
- Understanding consumers' decision contexts and prior beliefs;
- Providing adequate, comprehensible measures for the full range of consequences;
- Recognizing that value trade-offs are dependent on individual preferences and tastes; and
- Supporting consistency checks, to help people make decisions consistent with their preferences (Keeney, 2002).

Interpretation of new messages—including labels, warnings, and risk communications—depends on prior knowledge and beliefs (Sattler et al., 1997; Argo and Main, 2004), ethnic and cultural background (Burger et al., 1999a,b; Bostrom and Löfstedt, 2003; Knuth et al., 2003), and other characteristics of individual message recipients, as well as attributes of the messages. In addition to specific content (Bostrom et al., 1994) and attributes such as format, structure, graphics, and wording choices (Schriver, 1989; Atman et al., 1994; Wogalter et al., 1996; Sattler et al., 1997; Schriver, 1997), how messages are processed depends also on the reader's attributes and motivation, and the salience and importance of the topic to the reader (Wogalter et al., 1996; Zuckerman and Chaiken, 1998).

Knowing how consumers make such decisions is also critical to assessing the likelihood of success of different communication strategies. Hence the design of consumer information about benefits and risks associated with seafood consumption requires assessing the decision goals and decision processes of consumers through formative analyses involving interviews or focus groups, and observational studies, as well as quantitative survey analyses and experimental testing of presentation formats and dissemination outlets. The following discussion summarizes the evidence to date regarding the effects of seafood advisories, labels, point-of-purchase information, and other consumer communications.

Evaluating the Effects of Previous Seafood Consumption Guidance

Evaluating the impact of previous guidance on seafood purchasing behavior can be done either qualitatively or quantitatively. Focus groups have been the traditional qualitative method; responses to surveys provide the quantitative information (Source: http://www.cfsan.fda.gov/~dms/admehg3g.html). Simulations, predictions, and scenarios also can be employed.

Impact of Federal Fish Advisories

In a report to the Interagency Working Group on Mercury Communications, Levy and Derby (2000) described the results of eight focus groups conducted prior to the 2001 US EPA fish advisory. They characterize prior concerns about mercury in fish as low, with the perception that mercury in fish is primarily a pollution problem. Reactions to statements about hazards of mercury in fish and fish consumption advice were interpreted as demonstrating two kinds of spillover effects. The first was a failure to narrow the perception of the at-risk group to be pregnant women who eat a lot of fish; focus group participants concluded that the general public must be at risk for consuming mercury from fish. The second was a general tendency to categorize fish as safe or not without paying much attention to quantitative consumption advice. Also noted was the fact that participants wanted information on fish that were safe to eat as well as on those that were not safe to eat.

Oken et al. (2003) and Shimshack et al. (2005) conducted post hoc analyses of the effects of the 2001 US EPA fish advisory on seafood consumption. Oken et al. (2003) found that issuance of the advisory was correlated with decreased consumption of "dark meat" fish, canned tuna, and "white meat" fish in a study of pregnant women. However, it is unclear whether the decrease is attributable to the advisory because the study lacks controls for other known possible influences on consumption. Shimshack et al. (2005) find evidence suggestive of a decrease in canned fish consumption

after the advisory among those who regularly read newspapers or maga - zines. Overall, they conclude that the advisory had an effect in that over the period studied the mean expenditure share for canned fish fell for some targeted consumers compared to nontargeted consumers. Again, the study does not control for other factors that may have an important influence on changes in consumption. In addition, neither study controls for actual awareness of the advisory, which makes any attribution of the observed changes difficult. The business press refers to a drop in demand after the joint 2004 US EPA/FDA fish advisory (e.g., Warner, 2005). The committee cannot evaluate these claims due to the lack of any statistical information and controls for other factors that affect sales beyond the effects of the advisories. To the best of the committee's knowledge there have been, to date, no studies done by government, industry, academia, consumer, or en- vironmental groups that offer a credible measure of market impacts of the 2004 US EPA/FDA fish advisory.

Cohen et al. (2005) carried out simulations of consumer behavior under what they call optimistic, moderate, and pessimistic scenarios for responses to the 2001 advisory. Their optimistic scenario assumes that only women of childbearing age respond to the advisory, and do so by substituting low-mercury seafood for higher mercury seafood. Their moderate scenario assumes that women of childbearing age reduce their seafood consumption by 17 percent in response to the 2001 advisory, with no change in types of seafood consumed. Their pessimistic scenario assumes that all adults decrease seafood consumption by 17 percent. In both the moderate and pes simistic scenarios, an overall decrease in benefits results (estimated changes in Quality Adjusted Life Years from a benefit-risk analysis). The optimistic scenario estimates an increase in net benefits if there is compliance with the 2001 advisory, with no spillover effects. The greatest benefit is derived from eating one fish meal a week, as opposed to none. In summary, the analysis by Cohen et al. suggests that the advisory was appropriate, in theory; but the study is not an empirical evaluation of the effects of the advisories. Further, the study assumed some coronary and stroke risk-reduction benefits that recent reviews suggest may not be empirically substantiated.

The US EPA and FDA carried out two sets of focus group studies prior to issuing their joint 2004 US EPA/FDA fish advisory, for a total of 16 focus groups in seven locations (SOURCE: http://www.epa.gov/waterscience / fishadvice/factsheet.html). In a public presentation, an FDA spokesperson summarized findings from the first eight focus groups in four main points: (1) most participants preferred a simple message conveying that consum - ing high amounts of methylmercury may harm a child's development, and what to do to avoid high amounts; (2) some participants wanted more information about how methylmercury would affect health, and more data on particular species of fish; (3) some participants think of fish consump -

tion as a whole, and do not distinguish between commercially and sport- or recreationally caught fish; (4) almost all participants reported that they and their children would avoid species designated "do not eat," regardless of whether or not they were in the targeted audience (Davidson, 2004).

Detailed reports from these focus group studies are not available, although information shows that the focus groups included pregnant or lactating women and racially diverse groups of both sexes, and were conducted in coastal as well as noncoastal locations (Davidson, 2004).

Impact of State Fish Advisories

Survey evaluations suggest that awareness of state fish advisories is low overall. Between one-half and two-thirds of sports fishers reported awareness of state or local advisories in studies of advisory effectiveness (Burger and Waishwell, 2001; Anderson et al., 2004). Tilden et al. (1997), Anderson et al. (2004), and Knobeloch et al. (2005) found that awareness was higher among males than females, with less than half of the women who consume recreationally caught fish aware of advisories.

Risk information of the type found in fish advisories appears to increase reluctance to consume seafood proportionately to benefits when the risks are low, and without regard to benefits when the risks are high (Knuth et al., 2003). Further, there is preliminary evidence suggesting that risk-risk information (comparing the risks of seafood with risks of other foods) may influence risk perceptions more than benefit-risk information (for risks and benefits of seafood) (Knuth et al., 2003).

As is shown in Table 1-2 and Appendix Table B-3, seafood advisories and guidance have been issued by federal, state, and local authorities with conflicting objectives and differing assumptions, even to the point of inconsistent serving sizes. Even an expert reader would find it challenging to integrate these different pieces of advice with one another.

In general, it requires careful experimental design to be able to attribute the effects of specific communications (Golding et al.,1992; Johnson et al., 1992). Experimental evidence shows that warnings can change perceptions and beliefs (Wolgater and Laughrey, 1996; Sattler et al., 1997; Burger and Waishwell, 2001; Riley et al., 2001; Argo and Main, 2004; Knobeloch et al., 2005), but unintended effects, such as overreactions, may occur (Wheatley and Wheatley, 1981; Levy and Derby, 2000; Shimshack et al., 2005).

Labeling Effectiveness and Effects of health Claims

While there is little evidence pertaining to seafood labels per se, there is considerable evidence on labeling effectiveness in general. In their systematic review of 129 studies, Cowburn and Stockley (2003) concluded that most

consumers claim to look at nutrition labels at least sometimes, but actual use is not widespread. Evidence on consumer understanding of nutrition labels is mixed; while nutrition labels appear to enable simple comparisons, consumers have difficulty using them for more complex tasks, like placing food into consumers' overall dietary context. The review summarizes findings on label formatting as well, and recommends using boxes for the information; standard, familiar, consistent formatting; and thin alignment lines. Other formatting information reviewed suggested that pie charts are difficult for consumers to understand and should not be used, and that consumers using bar charts tended to compare the length of the bars without taking note of the scales (Cowburn and Stockley, 2003). Recent formative research on more graphic presentation of nutritional information suggests that "traffic light" formats (Food Standards Agency, 2005) may be effective. These rely on the familiarity of the traffic light metaphor, and the ease with which people interpret their colors.

Research on Qualified Health Claims as Applied to Functional Foods In their survey of consumers in Finland, Denmark, and the United States (n=1533, stratified by country), Bech-Larsen and Grunert (2003) found that perceived healthiness of functional foods was primarily determined by the perceived healthiness of the base foods (orange juice, yogurt and non-butter spread) used in their experiment regardless of the additional functional component. Health claims on the label increased the perceived healthiness of functional foods (Bech-Larsen and Grunert, 2003; Williams, 2005).

The optimal presentation of health claims may be a short health claim on the package front, with a longer panel on the back (Wansink et al., 2004). While health claims can change attitudes toward foods, qualifying such claims appropriately based on the quality of the underlying science is a challenging communications task. In tests of several formats, including adjectives embedded in statements and various report card formats (Derby and Levy, 2005), strength-of-science disclaimers did not have the intended effects.

Table 6-2 summarizes the current seafood consumption information environment. Information from the table can be used to identify opportunities for improving this environment with existing information. As illustrated in the table, the most salient gap is insufficient evaluation of the current consumer seafood information environment (e.g., marketing research) and a lack of emphasis on benefits of seafood consumption. Most information available focuses on risks alone. Other shortfalls include the limited reach of state advisories, lack of or potentially misleading (out of date, or inappropriate use of Reference Dose [RfD]) use of quantitative benefit and risk information in interactive online consumer guidance, and limited provision

TABLE 6-2 Summary of Current Seafood Consumption Information Environment

	Benefit/Risk Message	Source	Medium/Channel	Intended Audience(s)	Available Evaluation Evidence
Federal Advisories	Mercury risks	FDA, US EPA	Mass media, broadcast	Females of childbearing age, infants, and children	Insufficient evaluation of market impact Suggestion of spillover effects, including possible stigmatization of seafood (Levy and Derby, 2000; Davidson, 2004)
State Advisories	Risks: 30 percent on mercury	State health and environmental agencies	Brochures, government websites, signs	Various	Evaluations suggest limited effectiveness One-fifth to one-half of sports fishers are aware of state or local advisories in studies of advisory effectiveness (Burger and Waishwell, 2001; Anderson et al., 2004)
Regulated Point-of-Purchase Information	Nutritional information, country of origin, risk	Safeway, Albertson's, Wal-Mart, Whole Foods, etc.	Point-of-purchase placards, shelf tags, pamphlets/ brochures; individual food wrappers and stickers on the outside of food	All consumers	Suggestion that these displays can increase market share of product by 1–2 percent over 2 years (Cowburn and Stockley, 2003) No specific evaluations of point-of-purchase displays of mercury in seafood; evaluations of point-of-purchase displays for seafood source suggest false claims are made regarding origin (Burger et al., 2004)
Labeling	Types of seafood and how much to consume; nutritional information and risks	Retailers	Point-of-purchase placards, shelf tags, pamphlets/ brochures; individual food wrappers and stickers on the outside of food	All consumers	Most consumers claim to look at nutrition labels at least sometimes, but actual use is less widespread (Cowburn and Stockley, 2003) No specific evaluation of seafood labels—limited labeling requirements

Qualified Health Claims	Eating foods high in omega-3 fatty acids to decrease risk of heart disease	Producers	On products/menus	All consumers	These claims increase the perceived healthfulness of functional foods (Bech-Larsen and Grunert, 2003; Williams, 2005)
Web-based Health Information	Nutrition information (although often not updated), risk, mercury, Dioxin-like Compounds, ecological	Environmental Non-governmental Organizations	Internet, interactive	Internet users, environmentally concerned	Committee unaware of any evaluations. Advice is given in a limited number of categories; limited quantitative information; very limited info on benefits of seafood consumption
Mercury Intake Calculators	Risk focus: mercury	Various organizations (public health, environmental action, nonprofit, education/campaign, research advocacy)	Internet, interactive	Internet users, concerned consumers (inferred)	Misuse of RfD, committee unaware of any evaluations
Northern Contaminants Program	Benefits, balancing choices	Health Canada	Mixed media, participative program	Northern communities	Program limited to Northern Canada (Kuhnlein et al., 2000; Mos et al., 2004; Willows, 2005), evaluations suggest program effectively prevents substituting low nutrition foods for seafood; questions about costs

of point-of-purchase information. Notably, federal and state government agencies are not currently providing interactive online guidance.

SETTING THE STAGE FOR DESIGNING CONSUMER GUIDANCE

Seafood is a complex commodity, with a very wide range of individual products with varying price levels, and nutrient and contaminant profiles. The availability and affordability of seafood products is changing (see Chapter 2); this is likely to influence the ability of consumers to implement the seafood choices that they want to make to balance benefits and risks. The market context in which consumers make choices should be kept in mind when designing guidance. For example, information accompanying the guidance could point to lower-cost alternatives for increasing intake of seafood rich in EPA and DHA.

Seafood choices, like all consumption choices, entail value trade-offs; for example, seafood higher in EPA and DHA may cost more than seafood that is lower. Other seafood may be more economical but contain higher levels of contaminants. Some individuals will accept high risks to achieve what they value as high benefits (e.g., consume raw seafood because of its pleasurable taste), while others may prefer to "play it safe."

Individual differences in tastes, preferences, beliefs and attitudes, and situations complicate the task of informing and supporting benefit-risk trade-off decisions. Food choices may be predicated on different objectives—a healthy baby for the pregnant woman, or weight loss for someone who is overweight. Audience segmentation and targeting is essential for effective communication (see above), not only because decision objectives and risk attitudes vary, but because people's knowledge and interest varies.

Tailored communications are more effective than general advice (de Vries and Brug, 1999; Rimer and Glassman, 1999). For example, access to appropriate, science-based information on both the benefits and risks of seafood consumption is particularly critical for pregnant women to enable them to adhere to health guidance messages (Athearn et al., 2004). Therefore, constructing information on balancing the benefits and risks of seafood consumption during pregnancy must address pregnant women separately from other consumers.

A recent multi-state focus group study (Athearn et al., 2004) revealed that most but not all women were aware of and followed the recommendation to avoid undercooked or raw seafood during pregnancy. In contrast, the recommendation not to serve smoked fish cold without heating was less familiar, which was reflected in higher reported consumption levels (25.8 percent for smoked fish vs. 14.5 percent for undercooked or raw seafood consumption). This appeared to be related to lack of exposure to this recommendation (especially from participants' doctors) and lack of publicized

evidence of risk (in terms of outbreaks, case studies, or risk assessment measures). It was also related to the lack of clarity as to whether "smoked" fish included lox and hot-smoked and/or cold-smoked fish. The authors concluded that it is critical for pregnant women to understand why the information is being targeted to them, and to make certain to entitle food safety information as "applicable to pregnant women" specifically.

Consumer messages about diet and nutrition need to be understandable, achievable, and consistent across information sources. They must also "address sources of discomfort about dietary choices; they must engender a sense of empowerment; and they should motivate both by providing clear information that propels toward taking action and appeals to the need to make personal choices" (Borra et al., 2001). Consumers need access to information that is in a clear and easy-to-understand format, that is structured to support decision-making, and that allows consumers access to additional layers of information when they want them (Morgan et al., 2001).

It is important for those designing consumer guidance to conduct an empirical analysis of the decision-making process. Part of this assessment is understanding consumers' decision context when they are presented with guidance suggesting changes in food choice behavior. One way to gain such understanding is to construct an empirically based scenario reflective of the consumers' world, rather than that of the scientist, as described in the Family Seafood Selection Scenario shown in Appendix C-4. This should be based on the best available evidence from consumer research.

Pre-implemention and post hoc evaluation of the impact of consumer guidance must control for differences, as well as changes in factors including incomes and prices, that occur during the period studied in order to isolate the effect of the guidance itself. Otherwise, the effect of the guidance on changes in consumption may be over- or underestimated. These types of controls have been lacking in previous evaluations, making the effect of the guidance unclear.

FINDINGS

1. Consumers are faced with a multitude of enablers and barriers when making and implementing food choices. Dietary advice is just one component in making food choices.

2. Advice to consumers from the federal government and private organizations on seafood choices to promote human health has been fragmented. Benefits have been addressed separately from risks; portion sizes differ from one piece of advice to another. Some benefits and some risks have been addressed separately from others for different physiological systems and age groups. As a result, multiple pieces of guidance—sometimes conflicting—exist simultaneously for seafood.

3. The existence of multiple pieces of advice, without a balancing of benefits and risks, may lead to consumer misunderstanding. As a result, individuals may under- or overconsume foods relative to their own health situations.

4. There is inconsistency between current consumer advice in relation to portion sizes. For example, the FDA/US EPA fish advisory uses a 6-ounce serving size whereas nutritional advice from some government agencies uses a 3-ounce serving size.

5. Evidence is insufficient to document changes in general seafood consumption in response to the 2001 or 2004 methylmercury advisories.

6. It is apparent that messages about consumption often have to be individualized for different groups such as pregnant females, children, the general population, subsistence fishermen, and native populations.

7. Involving representatives of targeted subpopulations (e.g., Arctic Circle campaign) in both the design and evaluation of communications intended to reach those subpopulations can improve the effectiveness of those communications.

8. There are models for designing guidance, e.g., using full programs, that some individual communities (e.g., Arctic Circle campaign) have contributed to understanding the effects of different modes of health communication and modifying messages to achieve the desired community and/or individual response.

RECOMMENDATIONS

Recommendation 1: Appropriate federal agencies should develop tools for consumers, such as computer-based, interactive decision support and visual representations of benefits and risks that are easy to use and to interpret. An example of this kind of tool is the health risk appraisal (HRA), which allows individuals to enter their own specific information and returns appropriate recommendations to guide their health actions. The model developed here provides this kind of evidence-based recommendation regarding seafood consumption. Agencies should also develop alternative tools for populations with limited access to computer-based information.

Recommendation 2: New tools apart from traditional safety assessments should be developed, such as consumer-based benefit-risk analyses. A better way is needed to characterize the risks combined with benefit analysis.

Recommendation 3: A consumer-directed decision path needs to be properly designed, tested, and evaluated. The resulting product must undergo methodological review and update on a continuing basis. Responsible agencies will need to work with specialists in risk communication and evaluation, and tailor advice to specific groups as appropriate.

Recommendation 4: Consolidated advice is needed that brings together different benefit and risk considerations, and is tailored to individual circumstances, to better inform consumer choices. Effort should be made to improve coordination of federal guidance with that provided through partnerships at the state and local level.

Recommendation 5: Consumer messages should be tested to determine if there are spillover effects for segments of the population not targeted by the message. There is suggestive evidence that risk-avoidance advice for sensitive subpopulations may be construed by other groups or the general population as appropriate precautionary action for themselves. While emphasizing trade-offs may reduce the risk of spillover effects, consumer testing of messages should address the potential for spillover effects explicitly.

RESEARCH RECOMMENDATIONS

Recommendation 1: Research is needed to develop and evaluate more effective communication tools for use when conveying the health benefits and risks of seafood consumption as well as current and emerging information to the public. These tools should be tested among different communities and subgroups within the population and evaluated with pre- and post-test activities.

Recommendation 2: Among federal agencies there is a need to design and distribute better consumer advice to understand and acknowledge the context in which the information will be used by consumers. Understanding consumer decision making is a prerequisite. The information provided to consumers should be developed with recognition of the individual, environmental, social, and economic consequences of the advice. In addition, it is important that consistency between agencies be maintained, particularly with regard to communication information using serving sizes.

SUMMARY

Mass communication has inarguably changed the world, using a one-size-fits-all model. There are health messages that everyone of a certain generation has heard ("Just Say No"). But like shoes, advice is more helpful if it is sized appropriately and designed appropriately for the intended use. As communications technologies have advanced, the communicator's ability to tailor communications to reach large audiences rapidly, and interact with them, has also advanced.

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7

Balancing Choices: Supporting Consumer Seafood Consumption Decisions

This chapter presents Step 3 (see Box 5-1) of the process for designing consumer guidance on balancing benefits and risks associated with seafood consumption. This step focuses on the design and evaluation of the guidance program itself, including the format of the guidance; its communication through media, health care partners, and other channels; and mock-up examples of ways to integrate the benefit and risk considerations from previous chapters into consumer guidance. The chapter also discusses other communication and decision-support design considerations.

INTRODUCTION

The goal of this chapter is to advise agencies on how to develop a consumer seafood information program to support consumers who are trying to balance benefits and risks in their seafood consumption decisions. Such advice necessarily builds on an assessment of the benefits and risks, as well as an assessment of what decisions consumers actually face, and how they currently approach those decisions. A related and essential element of the process is use of the best available social and behavioral science research on the design of effective communications programs and messages to inform consumer benefit-risk decisions. In addition, we present several specific options for informing seafood consumption decisions, in order to highlight the features of alternative formats for informing consumers' seafood consumption decisions for themselves and their families.

While there is a role for simple slogans and overall guidance to the general population, the committee believes that it cannot be emphasized

too much that communications tailored for specific audiences are likely to be more effective and thus are an important element in communications programs. This is especially important for benefit-risk choices where target population groups differ in their risk susceptibility, and in the degree to which they are likely to benefit. For both education and marketing, understanding the audience and targeting it appropriately are critical.

A successful communications program starts with clear objectives and measurable goals, and includes the steps outlined in the two preceding chapters followed by implementation and evaluation, as discussed below. The development strategy should be iterative, such that program evaluation is built into the program from the outset and used to refine it over time. One widely used health communications program planning document, the National Institutes of Health "Pink Book" (SOURCE: http://www.cancer.gov/pinkbook), suggests these components for a health communications program plan: a general description of the program, including intended audiences, goals, and objectives; a market research plan (i.e., for researching the consumer context and choice process); message and materials development and pretesting plans; materials production, distribution, and promotion plans; partnership plans; a process evaluation plan; an outcome evaluation plan; a task and timetable; and a budget.

For demonstration purposes, the committee takes as a working objective the facilitation of consumer use of information for decision making and balancing choices, for a wide variety of consumers. Corresponding measurable end points would be increased awareness of both benefits and risks of seafood consumption, and increased ease of access and usability of seafood benefit-risk information.

Table 6-2 in Chapter 6 provides a summary of the current seafood consumption information environment. Opportunities for improving the current information environment include: (1) providing more comprehensive and systematic evaluation of current consumer seafood information and information environments for target populations ("marketing research"); (2) increasing the emphasis on benefits of seafood consumption; (3) assessing the overall role of state advisories in consumer seafood consumption decisions, taking into account their limited reach; (4) increasing the availability of quantitative benefit and risk data for seafood consumption, and addressing any errors in how quantitative benefit and risk information is used in interactive online consumer guidance; (5) increasing the use and usefulness of point-of-purchase displays; and (6) developing partnership programs.

Notably, while US federal and state agencies provide websites for consumers (e.g., http://www.foodsafety.gov/ ~fsg/fsgadvic.html; http://health.nih.gov), these do not currently provide interactive online guidance; other parties are now providing quantitative risk information, as discussed in Chapter 6. Much has been written about program evaluation (CDC, 1999;

Mark et al., 2000; Ryan and DeStefano, 2000) and the evaluation of communications (Schriver, 1990; Spyridakis, 2000); the paucity of information available regarding both formative (e.g., the Food and Drug Administration focus groups) and summative (e.g., overall effects on attitudes or consumption) evaluation of national seafood consumption advisories suggests that agencies should devote additional attention and resources to evaluation. The committee touches on the importance of evaluation in the context of partnerships, to assess whether communications are appropriate and effective for target populations.

STEP 3: DESIGNING COMMUNICATIONS TO SUPPORT INFORMED DECISION-MAKING

Interactive Health Communication

In seafood consumption, "one size does not fit all," and messages about consumption often have to be individualized for different groups. There is a need to consider developing tools for consumers such as web-based, interactive programs that provide easy-to-use seafood consumption decision tools. Real-time, interactive decision support that is easily available to the public has the potential to increase informed actions for some portion of the population. In the absence of federal investment in such tools, some organizations have invested in online mercury calculators or consumption guides (Table 6-1). Many of these focus solely on risks from seafood consumption, and while well-intentioned, may be providing misleading information, for example, by interpreting the Reference Dose (RfD) as a "bright line" to determine whether consuming seafood puts a consumer at risk.

One model for developing comprehensive consumer tools is a health risk appraisal (HRA) that would allow individuals to enter their own specific information and would provide feedback in the form of appropriate information or advice to guide the user's health actions, such as seafood consumption. There are a myriad of health risk appraisal tools commercially available; of those in the public domain the Centers for Disease Control and Prevention (CDC) has extensive experience in the development and use of HRAs (SOURCE: http://www.cdc.gov). In order to be most useful and appropriately directed, tools such as the HRA must be based on a body of knowledge that substantiates both benefits and risks. This kind of approach can be seen in the *Clinical Guide to Preˆenti ˆe Serˆices* from the Agency for Healthcare Research and Quality (AHRQ), which adopted recommendations based on medical evidence and the strength of that evidence in practice (USPSTF, 2001–2004).

The *Clinical Guide to Preˆenti ˆe Serˆices* is an example of an interactive health communication approach to providing one-on-one guidance, along

with the degree of evidence for that guidance, which is used to categorize a spectrum of recommendations. These tools are generally not set up to provide information to individuals, but rather to public health practitioners and individual care providers. Their recommendations are evidence-based but not easily translatable to the lay community. Although the *Clinical Guide to Preventive Services* is aimed toward practitioners, AHRQ has tried to make it understandable to the general public—e.g., if you are over 50, and have a risk factor, then get a mammogram.

A more coordinated approach is needed for developing and disseminating evidence-based recommendations to health care practioners that can then be provided to consumers. Such recommendations should be updated on a continuous, rotating basis, to allow for more rapid translation of science to practice. Where HRA tools are targeted for intermediaries who are experts in their own right, guidance or additional tools are necessary to help them translate and target information for consumers. The *Clinical Guide to Preventive Services* has a handbook that attempts to provide user-friendly tools to help providers translate and target information to consumers. If the goal is to guide consumption decisions that balance benefits and risks, there needs to be a similar translation mechanism because of the limited and continuously evolving knowledge base concerning seafood benefits and safety. Currently, consumers are receiving piecemeal information about methylmercury and persistent organic pollutants such as dioxins and polychlorinated biphenyls (PCBs); for the most part, that information is not pulled together sufficiently to facilitate consumers' understanding it in context and thus being able to use it to inform their choices (see Table 6-2). (Also see Chapter 6 for discussion of the effectiveness of online nutrition information.)

A general framework for developing this kind of communication is a consumer checklist that engages the user in interactive identification of his or her benefit-risk factors, and uses that information to produce a tailored benefit-risk estimation and associated recommended actions. Determining how to communicate the resulting estimates and actions requires a series of judgements, including whether and how to represent this information as text, numbers, or graphics. Empirical testing of the effects of the final tool is essential, given the difficulties of predicting the effects of communications on individual consumers, or even specific target populations.

Decision Support for Consumers

The committee's balancing of the benefits and risks of different patterns of seafood consumption for different target populations resulted in the analysis presented in Chapter 5. This type of expert identification of the characteristics that distinguish target populations who face substantially dif-

ferent consequences from seafood consumption is an important component of audience segmentation and targeting.

If a target population believes they are exempt from general advice because of some specific condition, they may either ignore the available advice or interpret it in unanticipated ways. The spillover effects discussed in Chapter 6 illustrate the kinds of problems that may arise. While expert recommendations such as those summarized in Chapter 5 could, in theory, be used directly by federal agencies as advice to consumers on seafood consumption, such advice is unlikely to be effective if it ignores consumers' contexts and information needs.

As discussed in Chapter 6, there are multiple reasons why expert benefit-risk analyses alone comprise an insufficient communication design strategy. Examples include when consumers distrust experts, when there are widespread misconceptions about a risk or benefit, or when experts use technical jargon that makes their reasoning opaque to nonexperts. Some consumers may want more information, and some will want to be able to independently verify experts' advice.

One previously tested consumer-centered approach to providing information is the development of decision support focused on the decisions and decision contexts faced by consumers, as discussed in Chapter 6. Through a brief set of questions, a decision pathway can segment and channel consumers into relevant target populations in order to provide benefit and risk information that is tailored to each group, as illustrated in Figures 7-1 and 7-2.

Figure 7-2 includes a separate question about cardiovascular health, which differentiates it from Figure 5-2. This question is included because the committee anticipates that the many recommendations and guidelines specially targeting higher eicosapentaenoic acid/docosahexaenoic acid (EPA/DHA) consumption for those with cardiovascular health concerns may have created a belief in that target population that they would benefit more than others from high EPA/DHA consumption. As is evident from the recommendations in both Figure 5-2 and 7-2, the committee's analysis does not support this distinction. This assumption about cardiovascular patients' beliefs would need to be verified empirically before it was included as part of a communications program.

Alternative formats for presenting information can serve the interests of consumers who desire different levels of information as inputs to their decision-making, and provide those most interested with additional insight regarding the quality of information, including uncertainties. Alternative guidance structures might be relevant for consumers focused on different goals and decisions, such as the estimated benefits and risks of eating a specific seafood meal, as illustrated in Figure 7-3. Figure 7-3 uses consumption of one 3-ounce serving of Atlantic farmed salmon as an example of the type of information that could be presented with this tool. The committee notes

1. What is your age?
   - ☐ 2-19
   - ☐ 20-39
   - ☐ 40+

2. What is your sex?
   - ☐ Male
   - ☐ Female

   If female, could you become pregnant or are you currently pregnant or lactating?
   - ☐ Yes
   - ☐ No

3. Are you at risk of cardiovascular disease?
   - ☐ Yes
   - ☐ No

4. Do you eat fish caught in local waters, as opposed to commercially available fish?
   - ☐ Yes
   - ☐ No

FIGURE 7-1 Example of set of questions to identify benefit-risk target populations for seafood consumption.

that the eocological effects of increasing salmon aquaculture are highly debated (e.g., Naylor et al., 2001). Further consideration would have to be given to this debate if the decision tool were to also incorporate a weighing of the ecological impacts of food choices.

Another alternative format structure might be a comparison of two meal options, as illustrated in Figures 7-4a and 7-4b for the example of consuming a serving of salmon vs. a serving of chicken. Full development of this comparison approach would require information, such as that shown in Table 5-1, on a full range of seafood and other food products that consumers may substitute for each other.

Decision analyses can be presented in several formats (e.g., Figures 7-3, 7-4a, and 7-4b) or used to lead consumers through a decision pathway, for example, via an interactive Web-based program that graphically provides tailored information. In a Web-based format, the consumer could proceed by answering a set of questions such as those shown in Figure 7-1.

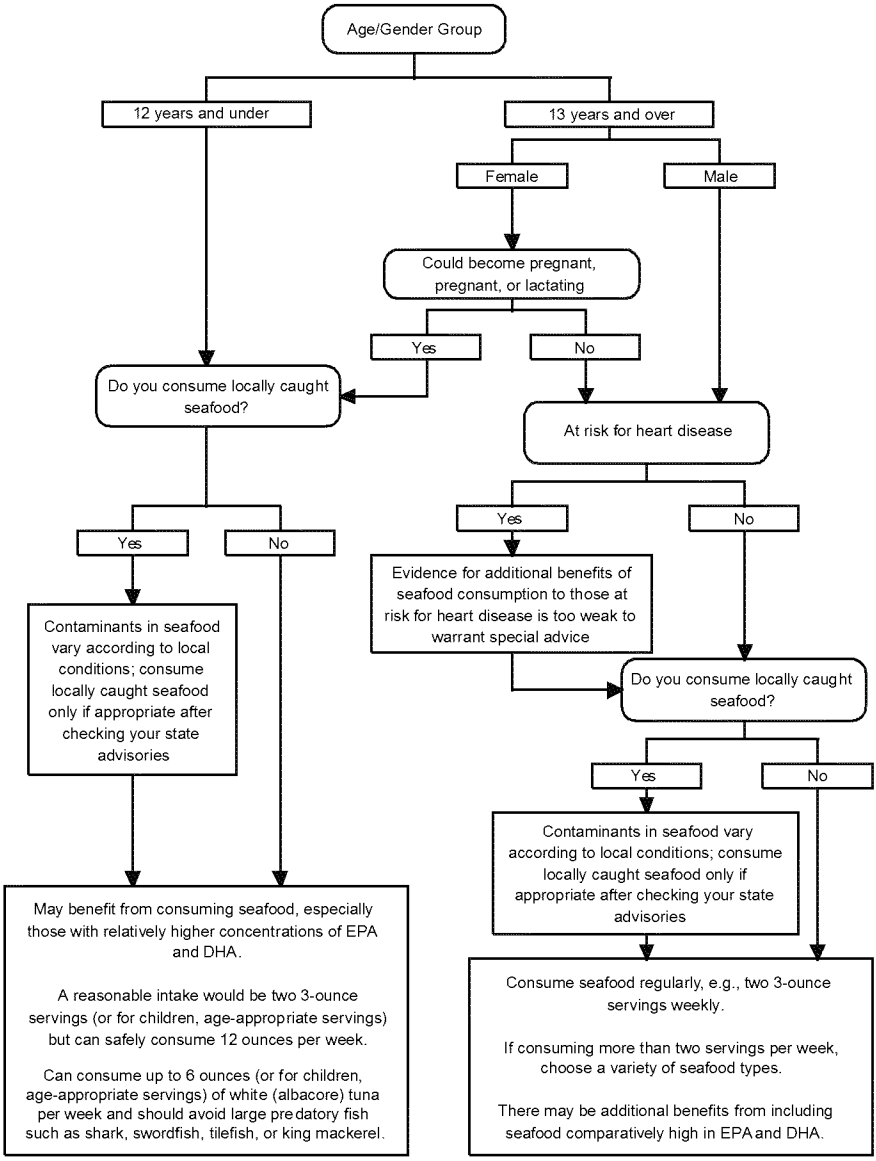

FIGURE 7-2 Example of a decision pathway for consumer guidance.
NOTE: The wording in this figure has not been tested among consumers. Designers will need to test the effects of presenting information on seafood choices in alternative formats.

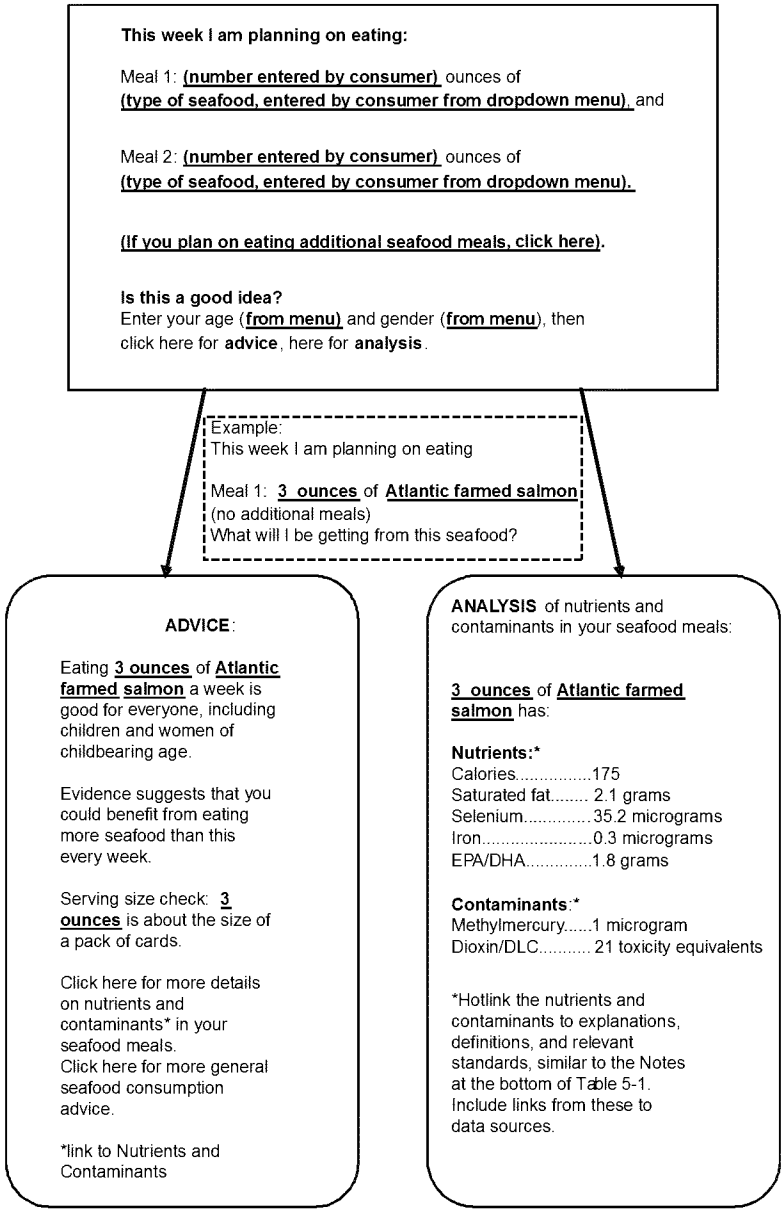

FIGURE 7-3 Example of seafood meal analysis decision tool—Would I receive a benefit or risk from eating this seafood meal? Questions: portion size (3 or 6 ounces), kind of seafood (all of the most commonly eaten kinds), specific species/type (where applicable and data available—e.g., for salmon).

What happens if I eat 3 ounces of salmon inste ad of 3 ounces of chicken?

Tabular Comparison[a]

		Salmon (3 oz)	Chicken[c] (3 oz)
Nutrients	Energy (kcal)[b]	175	140
	EPA/DHA (g)[b]	1.8	0.03
Contaminants	Methylmercury (μg)[b]	1	0
	Dioxin/DLC (TEQ)[b]	21	2

FIGURE 7-4a Example of a substitution question approach with tabular presentation of information—What happens if I eat seafood X (e.g., salmon) instead of food Y (e.g., chicken)?

[a]Continue the table with other nutrients/contaminants/other factors of interest.
[b]Hot link the units to explanations and definition (for example, TEQ = sum of toxicity equivalency factors (TEF); where TEF is a numerical index that is used to compare the toxicity of different congeners and substances, in this case dioxin congeners.
[c]Note that EPA/DHA levels in chicken and eggs are based on existing published data; changes in the use of fishmeal in feed sources may have an impact on levels detected in the future.

The example decision pathway shown in Figure 7-2 distinguishes be - tween consumer target populations in order to tailor consumption advice based on current evidence regarding the benefits and risks of seafood con - sumption. It also assumes that consumers agree with and accept the health goals and risk assessments implicit in federal nutritional guidelines and risk advisories.

Additional information can be added to explain branching in the deci - sion pathway and the reasons for it. Designers will need to test the effects of presenting information on seafood choices in alternative formats. The first set of hypertext explanations would link the questions asked in the decision pathway to the research used to create the pathway, to explain the questions' relevance to assessment of benefits and risks, and to provide consumers with links to more detailed information on the personal benefits and risks associated with seafood consumption. Table 7-1 shows examples of the types of explanations that might be used as added information in the

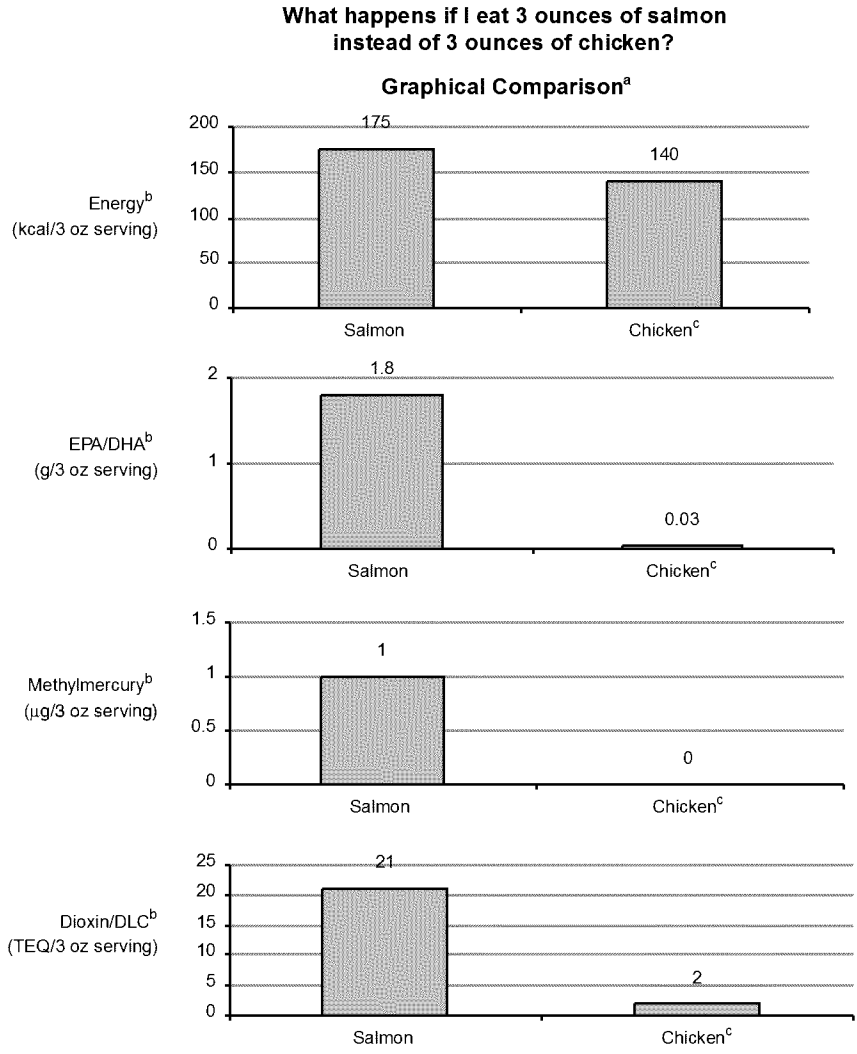

FIGURE 7-4b Example of a substitution question approach with graphical presentation of information—What happens if I eat seafood X (e.g., salmon) instead of food Y (e.g., chicken)?

[a]Continue the graphs with other nutrients/contaminants/other factors of interest.

[b]Hot link the units to explanations and definitions (for example, TEQ = sum of toxicity equivalency factors (TEF); where TEF is a numerical index that is used to compare the toxicity of different *congeners* and substances, in this case dioxin congeners.

[c]Note that EPA/DHA levels in chicken and eggs are based on existing published data; changes in the use of fishmeal in feed sources may have an impact on levels detected in the future.

TABLE 7-1 Examples of Possible Additional Layers of Information to Provide to Interested Consumers

	Possible Content of "Click Here for More Background Information"
Age	Children should eat age-appropriate portions. (hypertext link to table or pictures of age-appropriate portions)
Gender	Mercury accumulates in the body, and so can pose a risk to a nursing infant or future baby. This is why gender is important.
Pregnant, could become pregnant, lactating	Mercury accumulates in the body, and so can pose a risk to a nursing infant or future baby
Prior cardiovascular event	The evidence that suggests that those who have had heart attacks may reduce their risk by consuming EPA and DHA is weaker than previously thought. (link to additional data, source)
Seafood type, source, and preparation method	Explanatory paragraphs could summarize benefit and risk data for various species, by geographical origin (where data exist to distinguish in this way), and whether commercially available or self-caught fish. They could also discuss preparation methods—risks of raw fish (see Chapter 4) and cooking methods (e.g., frying, breading) that can abbrogate nutritional benefits. Current data do not support distinctions between seafood types beyond those made in the Food and Drug Administration/US Environmental Protection Agency 2004 advisory.
Alternative sources of nutrients; benefits, risks, and costs of alternatives	As addressed in Chapters 3, 4, and 5, other foods and fish-oil supplements are also sources of EPA and DHA. Other trade-offs identified in Chapter 5 could also be summarized for consumers. Regular updating would be necessary, given that changes in the use of fishmeal and other content in feed has changed and will change the nutritional value of animal products.

formats. Designers will need to test the effects of presenting information on seafood choices in alternative formats.

Presenting Quantitative Benefit-Risk Information: The Promise and Peril of Visual Information

Both anecdotal and experimental evidence support the use of visual information as superior to either text or numbers in many contexts. The inclusion of alternative presentations of benefit-risk information in the design of consumer advice recognizes that while some consumers prefer to follow the advice given them by experts, others want to decide on the benefit-risk trade-offs for themselves. Consumers differ in their ability to interpret spe-

cific benefit or risk metrics. As discussed in Chapter 6, effectively informing decision-making requires the use of metrics that consumers can evaluate and use. A consumer-centered information design and evaluation approach is needed that makes information "easily available, accurate, and timely" (Hibbard and Peters, 2003). One approach is to present numerical information graphically (Hibbard et al., 2002). Consumers should be familiar with rating systems that represent benefits and risks in a small number of categories (often five), as is done for crash test ratings (TRB, 2002). The UK Food Standards Agency (FSA) has proposed "red-amber-green" multiple traffic light labeling for foods (FSA, 2005, 2006; http://www.food.gov.uk/foodlabelling/signposting/signpostlabelresearch/).

Graph comprehension depends on experience and expectations, as well as on the design of the graph in question (Shah and Hoeffner, 2002). Familiarity with an analog, as in the multiple traffic light system proposed by the FSA, can aid comprehension. Consumer testing carried out by Navigator for FSA (FSA, 2005) suggests that the multiple traffic light system helps consumers choose more nutritious foods, although the system has been criticized for its simplicity (Fletcher, 2006). Other common graphical approaches to presenting benefits or risks include "thermometers," rank-ordered bar charts, or a more complex graphic embedded in a matrix of benefit and risk information, as is done by *Consumer Reports*.

While some of these approaches have been tested empirically, an agency developing consumer guidance should test prototypes on representative consumers. A potential problem in presenting benefit and risk metrics together is that the consumer may misinterpret the relationship between benefit and risk. For example, consumers are likely to infer that side-by-side thermometers or bars are directly comparable, even if they are labeled with different numerical scales.

Formats such as those presented by the committee in Figures 7-2 through 7-4b can serve as suitable advice for consumers who want general guidance on seafood consumption. However, other consumers may want specific information for different seafood products. In Navigator's testing, consumers preferred additional text to be informational rather than advisory (FSA, 2005). For these consumers, there is a large family of graphics that could be used to present choices across a broad range of seafood products. The committee developed several examples of graphical presentations of guidance to illustrate possible approaches. In presenting such graphics, the committee emphasizes its finding that it is not possible to have a single metric that captures complex benefit-risk relationships. Any sort of score system is unlikely to capture the inherent uncertainties in what is known about the underlying benefit-risk trade-offs. Graphical formats should be carefully and empirically tested to insure that they effectively communicate with consumers.

Multiple design decisions are required to produce graphical guidance; all could influence the impression the consumer takes away. These decisions include the selection of the seafood types to show; the colors, order, and formatting of bars to use; and whether to employ error bars to communicate uncertainty about point estimates. The graphical examples presented in Figures 7-5 through 7-8b below focus on information on EPA/DHA and methylmercury in seafood selections. A particularly important design choice here is the inclusion/exclusion and relative size of the scale of EPA/DHA bars as compared to the scale of methylmercury bars. Similar decisions would need to be made in presenting other benefit (e.g., low-fat profiles) and risk (e.g., other contaminants) information in these types of formats. In the figures presented here, the relative lengths of the EPA/DHA and methylmercury scales have been chosen arbitrarily, as the committee has not determined quantitatively the relative values of benefits from EPA/DHA and risks from methylmercury. The graphics present information that the consumer would use in conjunction with specific guidance that is appropriate for them (e.g., consumption of EPA/DHA, avoidance of methylmercury).

Figures 7-5 through 7-7 are examples of formats that could be tested with consumers. In the discussion here, the committee highlights considerations in the alternative approaches. All of these graphics relate to the benefit-risk tradeoff between EPA/DHA consumption and methylmercury intake. The use of this example reflects the fact that information is more complete here than for other nutrient and toxicant effects, not that these are the only benefit-risk tradeoffs that are relevant to consumers. However, the effect of graphics like these is likely to be to draw consumers' attention to this information, and to ignore other possibly relevant information.

Figure 7-5 emphasizes the EPA/DHA content of different fish in grams per 3-ounce serving. This monochromatic graph is intended to emphasize benefits and provide guidance on seafood choices to enhance EPA/DHA consumption. This figure may be appropriate by itself for the guidance of adolescent males, adult males, and females who will not become pregant. For females who could become pregnant, are pregnant, or are lactating, and for infants and young children, the graph might include colored bars (red and yellow) to indicate fish (e.g., tilefish) containing levels of methylmercury that increase the potential for adverse health effects for these groups.

Figures 7-6a and 7-6b combine the presentation of information on EPA/DHA and methylmercury levels in a 3-ounce serving for different types of seafood. Two versions of this graph are presented in order to emphasize the design issues involved. These issues arise from the fact that the committee could not use a single scale, quantitative metric (e.g., Quality Adjusted Life Year, Disability Adjusted Life Year) for the combined benefit-risk profile of different seafoods. Thus, the information for methylmercury and EPA/DHA must be presented in separate metric scales that are not directly comparable.

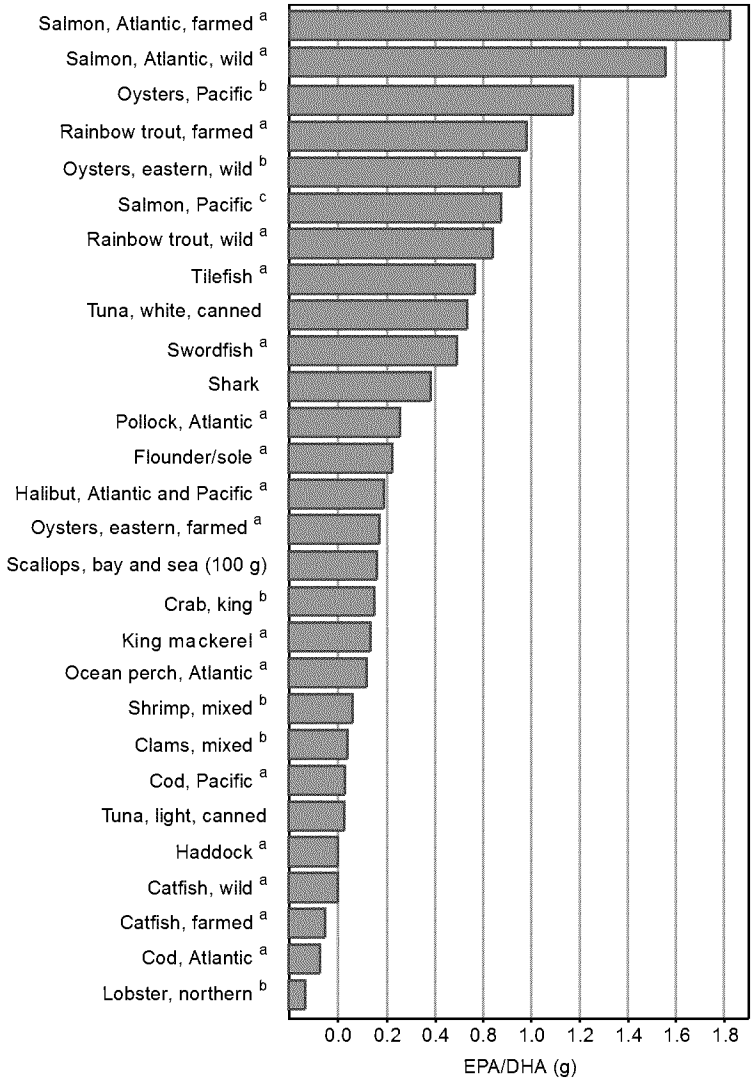

FIGURE 7-5 Estimated EPA/DHA amount (grams [g]) in one 3-ounce portion of seafood.
NOTES: The scale used in this figure for EPA/DHA content is arbitrary. Designers will need to carefully test the effect of the scale used for the bars on the message received by consumers.

[a]Cooked, dry heat.
[b]Cooked, moist heat.
[c]The EPA and DHA content in Pacific salmon is a composite from chum, coho, and sockeye.

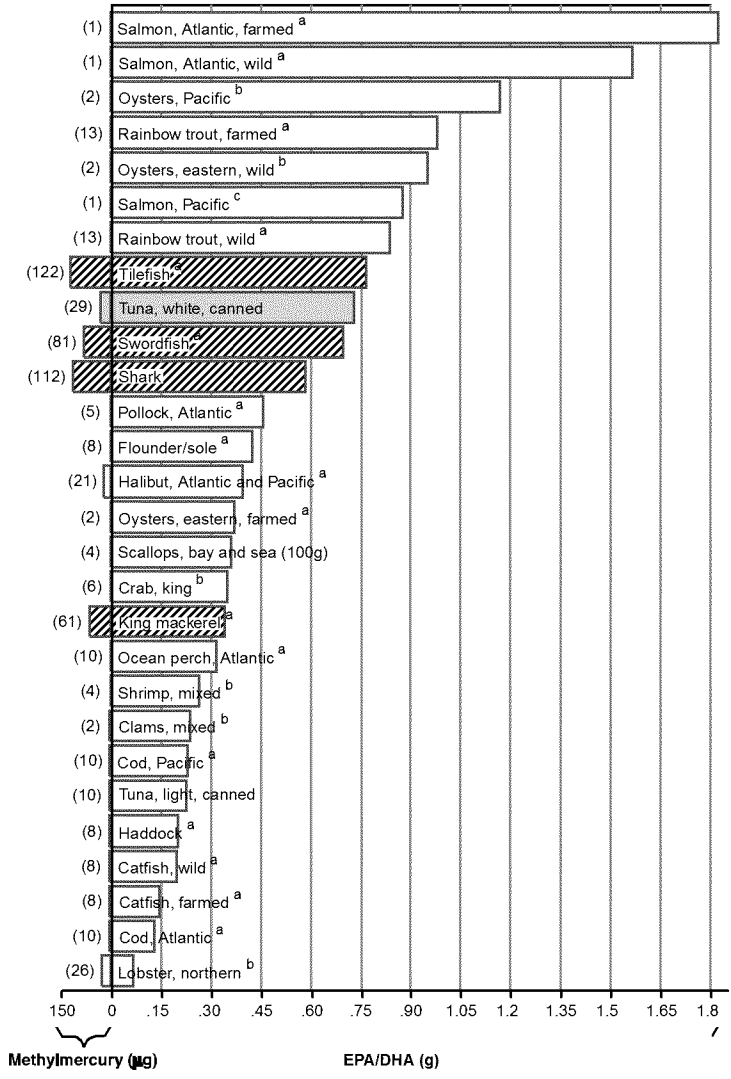

FIGURE 7-6a Example of estimated EPA/DHA (grams [g]) and methylmercury (microgram [∝g]) amounts in one 3-ounce portion of seafood.
NOTES: The scales used in this figure for EPA/DHA and methylmercury content are arbitrary. Designers will need to carefully test the effect of the scales used for the bars on the message received by consumers.

[a]Cooked, dry heat.
[b]Cooked, moist heat.
[c]The EPA and DHA content in Pacific salmon is a composite from chum, coho, and sockeye.

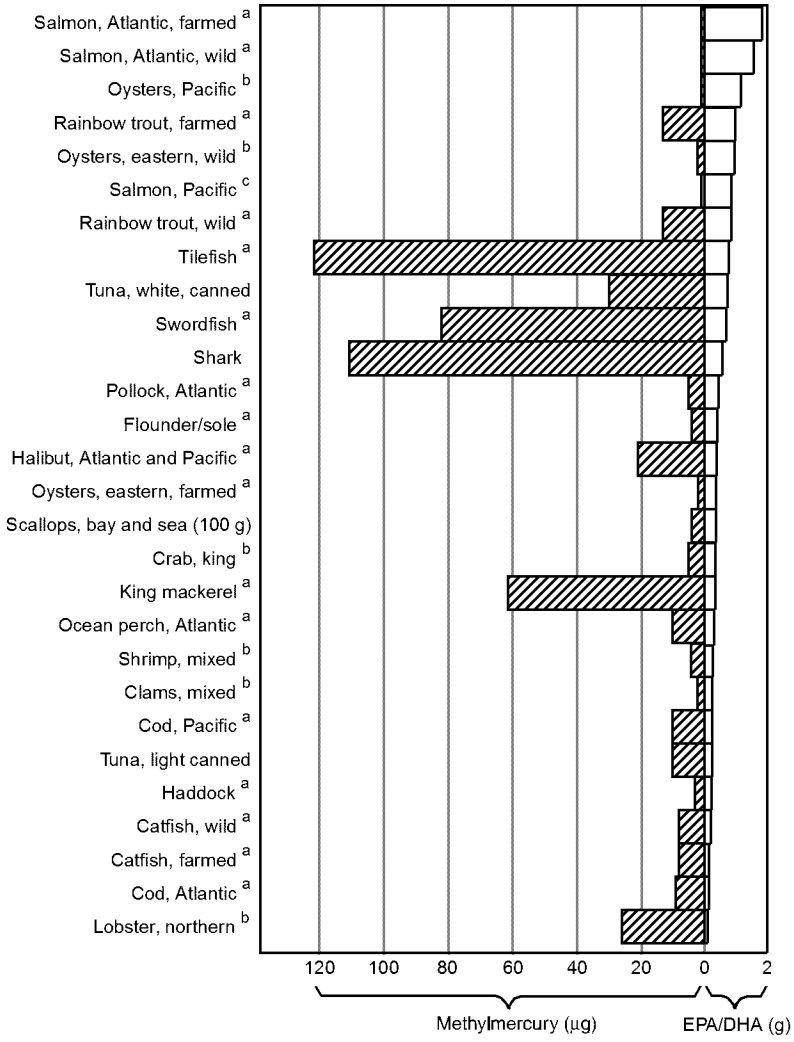

FIGURE 7-6b Example of estimated EPA/DHA (grams [g]) and methylmercury (microgram [∝g]) amounts in one 3-ounce portion of seafood, with emphasis on methylmercury.
NOTES: The scales used in this figure for EPA/DHA and methylmercury content are arbitrary. Designers will need to carefully test the effect of the scales used for the bars on the message received by consumers.

[a]Cooked, dry heat.
[b]Cooked, moist heat.
[c]The EPA and DHA content in Pacific salmon is a composite from chum, coho, and sockeye.

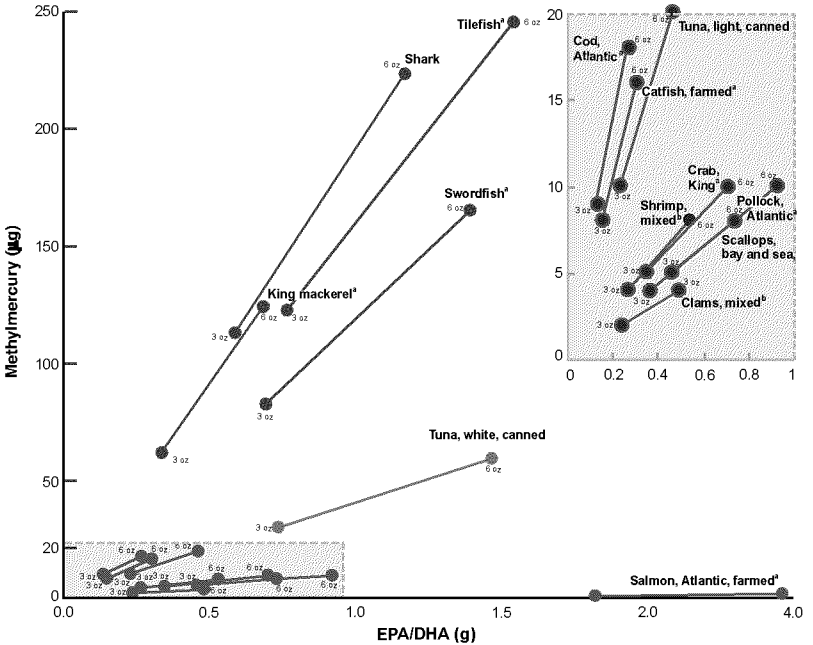

FIGURE 7-7 Estimated EPA/DHA (grams [g]) and methylmercury (micrograms [µg]) amounts in one and two 3-ounce servings per week amounts.
NOTES: The scales used in this figure for EPA/DHA and methylmercury content are arbitrary. Designers will need to carefully test the effect of the scales used for the bars on the message received by consumers.

[a]Cooked, dry heat.
[b]Cooked, moist heat.

Figures 7-6a and 7-6b illustrate that the choice of scales to use for each can greatly affect the graph's appearance. Testing with consumers is required to assess the impression made by alternative formats.

The scales used in Figure 7-6a have the effect of emphasizing information on EPA/DHA content and illustrate that there are a number of seafood choices, with varying levels of EPA and DHA, available with low exposure to methylmercury. The figure does not provide information about levels of lipophilic contaminants such as dioxins and PCBs because of the limited availability of data for various types of seafood. However, evidence presented in Chapter 4 suggests that levels of these contaminants in commercially obtained seafood do not pose a risk of adverse health effects even among the most at-risk groups, i.e., females who could become pregnant, are pregnant, or are lactating, and infants and young children, when consumed in the amount of two 3-ounce servings per week. As shown, Figure 7-6a may be appropriate for guidance to females who could become pregnant, are pregnant, or are lactating, and for infants and young children, as the shaded bars indicate types of seafood that should be avoided or consumed in limited amounts by individuals in these target populations. For adolescent males, adult males, and females who will not become pregnant, Figure 7-6a could be used for guidance without any specially shaded bars.

Figure 7-6b uses alternative scales to show the methylmercury and EPA/DHA content in 3-ounce servings of different seafoods. The design tends to emphasize the methylmercury and deemphasize the EPA/DHA information. A side-by-side comparison of Figures 7-6a and 7-6b illustrates the impact of design choices on how consumer guidance information is presented. The committee again emphasizes that the scales used in Figures 7-6a and 7-6b for EPA/DHA and methylmercury content are arbitrary. Designers will need to carefully test the effect of the scales used for the bars on the message received by consumers.

Figure 7-7 also provides information on both EPA/DHA and methylmercury content, although for a smaller number of seafood choices to make the figure easier to read. The figure's advantage is that it combines information on one and two 3-ounce servings per week. The corresponding disadvantage is that it may be harder for consumers to grasp. Graphs like this can be helpful in identifying product consumption patterns that provide benefits with little risk to most consumers as compared to those that raise risk concerns for some consumers. Figure 7-7 may be useful guidance for females who could become pregnant, are pregnant, or are lactating, and for infants and young children. If the EPA/DHA-methylmercury tradeoff is less important, for example, for adolescent males, adult males, and females who will not become pregant, then Figure 7-5, which focuses solely on EPA/DHA content, may provide more useful guidance. Here, the committee again notes that the choice of scale on the horizontal and vertical axes may

have an important effect on the message received by consumers. This effect should be carefully tested in the design phase.

Finally, Figures 7-8a and 7-8b illustrate the use of color to highlight information that is important to specific target populations. Figure 7-8a is a color version of Figure 7-6a. Seafood choices containing levels of methylmercury that exceed recommended safe intakes for females who could become pregnant, are pregnant, or are lactating, and for infants and young children and that should be avoided by these groups are shown in red. White (albacore) tuna is shown in yellow to indicate that consumption should be limited to 6 ounces per week for these at-risk population groups. Figure 7-8b, a color version of Figure 7-7, uses the same color scheme to emphasize choices for these groups.

The sample graphics presented here do not include a representation of uncertainty. Uncertainty can be represented with additional symbols (e.g., adding error bars), text or numbers, or with variations on the original graphic (e.g., by fading out the ends of the bars in a bar chart to indicate uncertain values or quantities. A consumer right-to-know perspective suggests that agencies are obligated to report or reveal uncertainties to interested consumers, and should strive to do so as transparently as possible. Representing uncertainty explicitly has the potential to improve decision-making (Roulston, 2006); failure to communicate uncertainty can increase public distrust (Frewer, 2004). However, testing is essential, as explicit representation of uncertainty can have unanticipated effects (Johnson and Slovic, 1995, 1998).

Given the weaknesses in the data underlying current conclusions on benefits and risks, strengthened collaboration between federal agencies appears to be an important goal for development of improved seafood consumption guidance. A federal advisory committee is one mechanism that could be used to coordinate across agencies.

In addition to collaboration between agencies, collaborating with non-traditional partners can assist federal agencies not only with dissemination of guidance, but with design and formative evaluation by engaging relevant target populations and providing a privileged relationship with them through the partnering organization. There are large networks of health care providers including but not limited to federal agencies that dispense daily advice on health and wellness and recommendations for medical care to broad segments of the population, including groups at high risk for poor health outcomes (SOURCE: http://www.healthfinder.gov). There are many opportunities to communicate benefit and risk information to at-risk population groups; a dramatic increase in immunization rates for children achieved in the mid-1990s illustrates one successful effort (CDC, 1996). A coordinated and tailored approach to individual consumer decision-making would have utility in working with federal agencies and other public health providers.

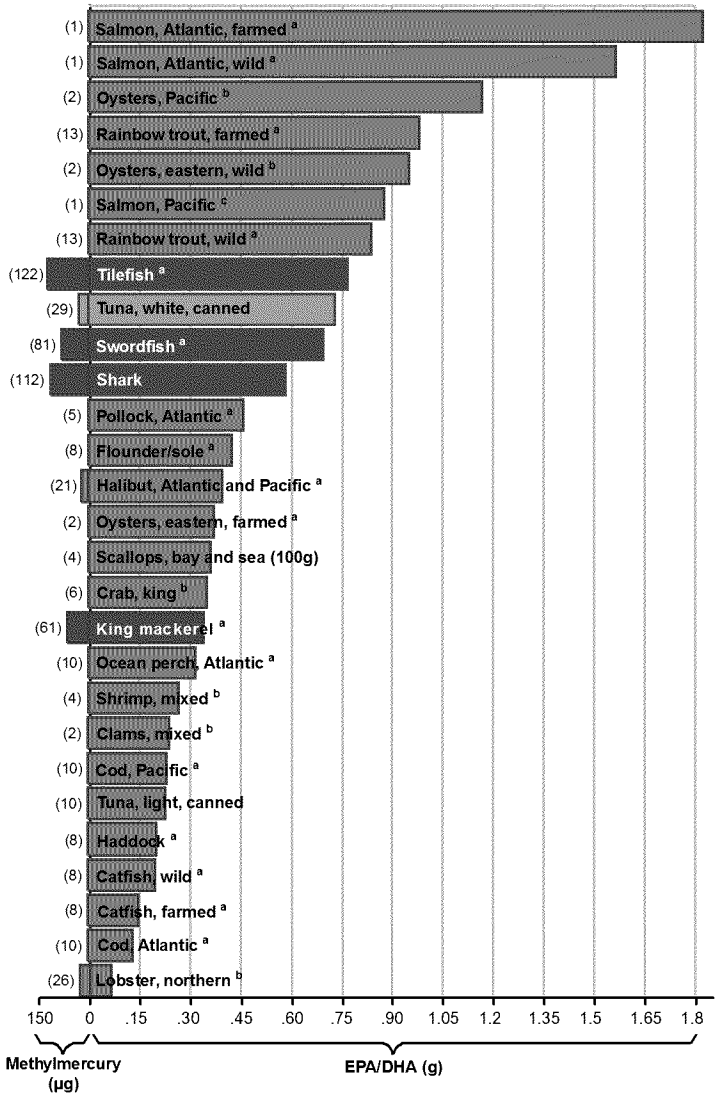

FIGURE 7-8a Color version of Figure 7-6a.
NOTES: The scales used in this figure for EPA/DHA and methylmercury content are arbitrary. Designers will need to carefully test the effect of the scales used for the bars on the message received by consumers.

[a]Cooked, dry heat.
[b]Cooked, moist heat.
[c]The EPA and DHA content in Pacific salmon is a composite from chum, coho, and sockeye.

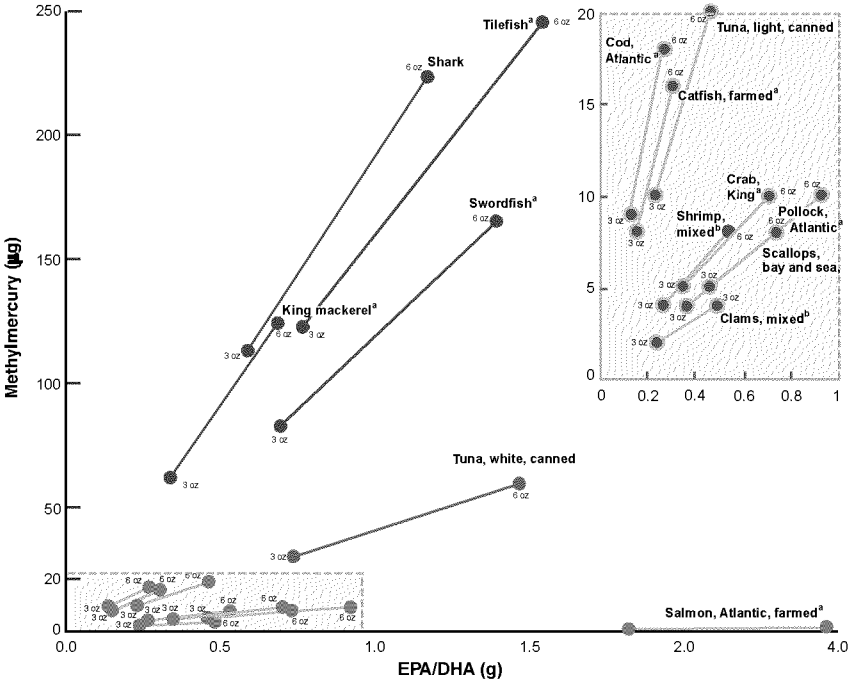

FIGURE 7-8b Color version of Figure 7-7.
NOTES: The scales used in this figure for EPA/DHA and methylmercury content are arbitrary. Designers will need to carefully test the effect of the scales used for the bars on the message received by consumers.

[a]Cooked, dry heat.
[b]Cooked, moist heat.

Communicating this information to these groups would often entail little or no increased cost. The limiting factor may be education of the providers (e.g., public health nurses) themselves. National associations could be an easy point of access for communicating information and networking (e.g., http://www.naccho.org).

Most state public health agencies, as well as many city and county agencies, have some statutory responsibility for seafood safety (advisories and posting regulatory actions, e.g., based on bacterial testing of oyster beds). Most of these agencies have health education programs including nutrition staff who provide individual counseling as well as health education to the general public. These agencies touch virtually every community and citizen in this country—there are more than 3000 local public health departments, not including county and state departments (SOURCE: http://www.naccho.org).

Community and migrant primary health care centers are funded through section 330 of the US Public Health Service Act and are charged with providing primary care and disease prevention services to low-income and other at-risk groups. Growth of their network has been a priority of the federal government, and the number of local sites exceeds 400, reaching millions of people daily (SOURCE: http://www.hrsa.gov). These centers are more often than not placed in communities at-risk. The community migrant health centers have also shown that when emphasis and training on disease prevention issues have been made a priority, disease (e.g., breast and cervical cancers) prevention interventions can actually exceed those provided to members of the general population who are not regarded as at risk. Community migrant health could be an important vehicle in helping consumers make informed seafood choices.

Collaborative Approaches: Federal Coordination and Communicating Health Messages Through Nontraditional Partners

There are a variety of federally funded but locally administered consumer education (e.g., Cooperative Extension System, see Box 7-1) and maternal-child health agencies (e.g., Title 5, Women, Infants, and Children Program [WIC], Head Start) that provide guidance and care to the general public, and to mothers and children. Although located in different agencies (e.g., WIC is administered through the US Department of Agriculture, Head Start is administered through the Administration for Children and Families [ACF]), these programs frequently serve either similar or the same populations. As with health partners in community health centers, they have a similar emphasis on health education and communication, and present significant opportunities for influencing consumer decision making.

BOX 7-1
Cooperative Extension

The Cooperative Extension is another nationwide educational network that delivers information to people in their homes, workplaces, and communities. Each US state and territory has a state office at its land-grant university and a network of local or regional offices. Extension links the resources and expertise of nearly 3150 county extension offices, 107 land-grant colleges and universities, and the federal government. County offices are staffed by one or more experts who provide useful, practical, and research-based information through printed and media-based materials, Web-based information sites, the telephone, community programs, and not-for-credit classes. This system is an excellent resource for disseminating health information and correcting misinformation.

The Need for Pretest and Post Hoc Evaluation

One of the challenges in supporting informed consumer choice is how governmental agencies communicate health benefits and risks to both the general population and to target populations. Previous attempts at communicating benefits and risks may have resulted in misinterpretation or misuse, including a reduction or total elimination of seafood consumption, by the intended audiences (Willows, 2005). Federal agencies should develop new and consumer-friendly tools to disseminate current and emerging information to the public. Developing effective tools requires formative evaluation, as well as an iterative approach to design.

Some individual communities have made substantial progress in understanding the effects of different modes of health communication and modifying the message to achieve the desired community and/or individual response. One such example is the Inuit community in Alaska, where communication of health risks from fish consumption previously resulted in changing patterns of food consumption from traditional foods to highly processed and often unhealthy alternative foods. Through the use of tailored messages and the involvement of the community throughout the entire process, a more effective message is now being provided to local communities.

Implementation: Embedding Consumer Advice Within a Larger Consumer Information Program

Consumers face challenging choices about seafood. Both the seafood

supply and the information about benefits and risks of consuming that seafood are changing rapidly. Fortunately, rapid advances in information and communication technologies now make it possible for agencies to distribute more up-to-date and detailed information, more widely, than ever before. Over 80 percent of US adults under age 40 use the Internet (Fox, 2005). This, however, does not negate the role of point-of-purchase information and the broader information context.

Further, there are communication structures in place within various federal agencies that are often duplicative and not effectively utilized. There is no functional mechanism in place for planning and implementing a new or evolving communication system that is synergistic and not duplicative. The committee is not aware of any significant efforts in place that would coordinate access to various programs within and between agencies and departments. There is potential for implementation of an effective system for communicating benefits and risks associated with consumption of seafood, but the means for implementation are not apparent. Achieving a coordinated and consistent approach that gives consumers information they can use and understand is likely to require some kind of coordinating mechanism, such as oversight by an interagency task force.

RECOMMENDATIONS

The committee offers the following general recommendations relevant to the design of seafood consumption advice.

Recommendation 1: The decision pathway the committee recommends, which illustrates its analysis of the current balance between benefits and risks associated with seafood consumption, should be used as a basis for developing consumer guidance tools for selecting seafood to obtain nutritional benefits balanced against exposure risks. Real-time, interactive decision tools, easily available to the public, could increase informed actions for a significant portion of the population, and help to inform important intermediaries, such as physicians.

Recommendation 2: The sponsor should work together with appropriate federal and state agencies concerned with public health to develop an interagency task force to coordinate data and communications on seafood consumption benefits, risks, and related issues such as fish stocks and seafood sources, and begin development of a communication program to help consumers make informed seafood consumption decisions. Empirical evaluation of consumers' needs and the effectiveness of communications should be an integral part of the program.

Recommendation 3: Partnerships should be formed between federal agencies and community organizations. This effort should include targeting

and involvement of intermediaries, such as physicians, and use of interactive Internet communications, which have the potential to increase the usefulness and accuracy of seafood consumption communications.

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A

Glossary and Supplementary Information

GLOSSARY

Abbreviations/Acronyms

5-HT	*In vivo* synaptic serotonin
AA	Arachidonic acid
ADHD	Attention Deficit Hyperactivity Disorder
AEDS	Atopic eczema/dermatitis syndrome
AHA	American Heart Association
AHR	Airway hyperresponsiveness
AHRQ	Agency for Healthcare Research and Quality
AI	Adequate Intake
ALA	Alpha-linolenic acid
ALSPAC	Avon Longitudinal Study of Parents and Children
AMI	Acute myocardial infarction
ANOVA	Analysis of variance
AOCS	American Oil Chemists Society
APC	Aerobic bacterial counts
APGAR	Activity, Pulse, Grimace, Appearance, and Respiration
APO	Apolipoprotein
APTT	Activated partial thromboplastin time
ARS	Agricultural Research Society
AUC	Area under the curve
BDI	Beck Depression Inventory

BMD	Benchmark dose
BMDLs	Benchmark dose lower bound
BMI	Body Mass Index
CAD	Coronary artery disease
CAPS	Childhood Asthma Prevention Study
CAT	Clinical Adaptive Test
CD	Cluster of differentiation (molecule)
CDC	Centers for Disease Control and Prevention
CDDs	Chlorinated dibenzo-*p*-dioxins
CDFs	Chlorinated dibenzofurans
CFR	Code of Federal Regulations
CGOST	Combined Cow and Gate Premium and Osterfeed formulae
CHD	Coronary heart disease
CI	Confidence interval
CLAMS DQ	Clinical Linguistic and Auditory Milestone Scale—Development Quotient
CNPase	2′,3′-cyclic nucleotide 3′-phosphodiesterase
CNS	Central nervous system
COPD	Chronic obstructive pulmonary disease
COT	Committee on Toxicity
CRP	C-reactive protein
CSFII	Continuing Survey of Food Intake by Individuals
CSPI	Center for Science in the Public Interest
CVD	Cardiovascular disease
DART	Diet and Reinfarction Trial; Diet and Angina Randomized Trial
DALY	Disability adjusted life years
DBD	Disruptive Behavior Disorders
DBP	Diastolic blood pressure
DDE	Dichlorodiphenyldichloroethane
DDST	Denver Developmental Screening Test
DDT	Dichlorodiphenyltrichloroethane
DGA	*Dietary Guidelines for Americans*
DGAC	Dietary Guidelines Advisory Committee
DGLA	Dihomo-gamma-linolenic acid
DHA	Docosahexaenoic acid
DHHS	Department of Health and Human Services
DNA	Deoxyribonucleic acid
DPA	Docosapentaenoic acid
DQ	Developmental quotient
DRI	Dietary Reference Intake

DSM	Diagnostic and Statistical Manual of Mental Disorders
DTA	Docosatetraenoic acid
ECG	Electrocardiogram
EFA	Essential fatty acids
EFSA	European Food Safety Authority
EPA	Eicosapentaenoic acid
EPDS	Edinburgh Postpartum Depression Scale
EPIC	European Prospective Investigation into Cancer and Nutrition
ETA	Eicosatrienoic acid
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FFQ	Food Frequency Questionnaire
FSA	Food Standards Agency (UK)
FVEP	Flash-visual evoked potential
GLA	Gamma-linolenic acid
GRAS	Generally recognized as safe
GSH-Px	Glutathione peroxidase
HACCP	Hazard Analysis and Critical Control Point
Hb	Hemoglobin
HDL-C	High-density lipoprotein cholesterol
HHS	Health and Human Services
HIV	Human immunodeficiency virus
HR	Hazard ratio
HRA	Health risk appraisal
HRT	Hormone replacement therapy
HSCL	Hopkins Symptom Checklist
HUFA	Highly unsaturated fatty acid
HVA	Homovanillic acid
IFN-≥	Interferon-gamma
IgG	Immunoglobin G
IgM	Immunoglobin M
IHC	Interactive Health Communication
IHD	Ischemic heart disease
IL	Interleukin
IMT	Intima-media thickness
IOM	Institute of Medicine

IQ	Intelligence quotient
IRR	Incidence rate ratio
ISAAC	International Study of Asthma and Allergy in Childhood
ISSC	Interstate Shellfish Sanitation Conference
JECFA	Joint FAO/WHO Expert Committee on Food Additives and Contaminants
K-ABC	Kaufman Assessment Battery for Children
KPS	Knobloch, Passamanik, and Sherrad's Developmental Screening Inventory
LA	Linoleic acid
LCPUFA	Long-chain polyunsaturated fatty acids
LDL-C	Low-density lipoprotein cholesterol
LNA	Linolenic acid
LOAEL	Lowest observed adverse effect level
MCDI	MacArthur Communicative Development Inventory
MDI	Bayley Scales of Infant Development Mental Index
MEC	Multiethnic Cohort Study
MFFT	Matching Familiar Figures Test
MI	Myocardial infarction
MPCOMP	Mental Processing Composite
MPN	Most probable number
NCP	Northern Contaminants Program
NHANES	National Health and Nutrition Examination Survey
NIH	National Institutes of Health
NLV	Norwalk-like viruses
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NOAEL	No observed adverse effect level
NONVERB	Nonverbal abilities
NRC	National Research Council
NYHA	New York Heart Association
OA	Oleic acid
OR	Odds ratio
OVA	Ovalbumin
PC	Phosphatidylcholine
PCB	Polychlorinated biphenyls

PCDD	Polychlorinated di-benzo-*p*-dioxin
PCDF	Polychlorinated di-benzo-*p*-furan
PCR	Polymerase chain reaction
PDI	Psychomotor Developmental Index
PE	Phosphatidylethanolamine
PGF2±	Prostaglandin $F_{2\pm}$
PHP	Post-harvest processing
PL	Phospholipid
Ppm	Parts per million
PT	Prothrombin time
PUFA	Polyunsaturated fatty acids
QALYs	Quality Adjusted Life Years
RBC	Red blood cell
RCT	Randomized clinical trial or randomized controlled trial
RDA	Recommended Dietary Allowance
RR	Relative risk
RRR	Relative risk reduction
RTE	Ready-to-eat
SACN	Scientific Advisory Committee on Nutrition (UK)
SBP	Systolic blood pressure
SCDS	Seychelles Child Development Study
SCID-CV	Statistical Manual of Mental Disorders, Fourth Edition, Axis I Disorders—Clinical Version
SE	Standard error
SEQPROC	Sequential processing
SIMPROC	Simultaneous processing
TCDD	Tetrachlorodibenzo-*p*-dioxin
TDE	Tetrachlorodiphenylethane
TDI	Tolerable Daily Intake
TEF	Toxicity Equivalency Factor
TEQ	Toxicity Equivalency
TF	Total fatty acids
TG	Triglycerides
TNF-±	Tumor necrosis factor alpha
TOVA	Test of Variables of Attention
UNEP	United Nations Environmental Programme
USDA	US Department of Agriculture
US EPA	US Environmental Protection Agency

VEP	Visual evoked potential
VLDL	Very low-density lipoprotein
VRM	Visual recognition memory
WHO	World Health Organization
WIC	Special Supplemental Nutrition Program for Women, Infants, and Children

Definitions

24-hour recall A method of collecting food consumption data; an interviewer solicits detailed information regarding what a study participant ate and drank in the previous 24 hours or on the previous day

Adipose tissue Fat tissue

Aflatoxin Any of a group of toxic compounds produced by certain molds that contaminate stored food supplies such as animal feed and peanuts

Analysis of variance (ANOVA) To identify sources of variability; to describe the relationship between a continuous dependent variable and one or more nominal independent variables

Anglers Those who crab and/or fish

Anthropogenic Of human origin

Aquaculture Rearing or cultivating marine or freshwater fish or shellfish under controlled conditions for food

Arrhythmia An irregular heartbeat

Assay The evaluation of a substance for impurities, toxicity, etc.

Atherosclerosis A condition in which plaques containing cholesterol and lipids are deposited on the innermost layer of the walls of large and medium-sized arteries

Atopic Of, relating to, or caused by a hereditary predisposition toward developing certain hypersensitivity reactions, such as hay fever, asthma, or chronic urticaria, upon exposure to specific antigens

Axonal The usually long process of a nerve fiber that generally conducts impulses away from the body of the nerve cell

Bayesian hierarchical model A statistical method to make inferences about an unknown parameter in a multi-level model

Benchmark dose modeling A technique for quantitative assessment of noncancer health effects; based on the level at which the prevalence of a defined health abnormality exceeds the background prevalence of the abnormality by a specified amount

Benefit-risk analysis Comparison of the benefits of a situation to its related risks

Best practices A technique or methodology that, through experience and research, has reliably proven to lead to a desired result

Bioaccumulative pollutants Substances that increase in concentration in living organisms as they take in contaminated air, water, or food because they are very slowly metabolized or excreted

Biomagnification The process by which the concentration of toxic substances increases in each successive link in the food chain

Body burden The total amount of a chemical in the human body or in human tissue from exposure to contaminants in the environment

Boston naming test A type of picture-naming vocabulary test used in the examination of children with learning disabilities and the evaluation of brain-injured adults

Calcarine fissure A narrow groove in the mesial surface of the occipital lobe of the cerebrum

Case-control study An epidemiological and observational study in which persons are selected because they have a specific disease or other outcome (cases) and are compared to a control (referent comparison) group without the disease to evaluate whether there is a difference in the frequency of exposure to possible disease risk factors; also termed a retrospective study or case referent study

Cerebellum A region of the brain that plays an important role in the integration of sensory perception and motor output

Chloracne A severe skin condition with acne-like lesions that occur mainly on the face and upper body after exposure to high doses of dioxin and dioxin-like compounds

Cholesterol The chief sterol in all animal tissues, especially brain, nerve, adrenal cortex, and liver; it functions as a constituent of bile and as a precursor of vitamin D; cholesterol circulates in the blood as lipoprotein, in combination with protein and other blood lipids

Ciguatera A natural toxin occurring sporadically in certain fish harvested from specific tropical to subtropical regions (i.e., South Florida, the Caribbean, and Hawaii)

Clostridium botulinum **(*C. botulinum*)** A specific microorganism that, under anaerobic conditions and thermal abuse, can produce an extremely potent toxin (destroyed by sufficient heating); produces spores that can be hazardous to babies, individuals on antibiotic therapy, or immunocompromised individuals

Cochrane review Systematic literature reviews based on the best available information about health care interventions. They explore the evidence for and against the effectiveness and appropriateness of treatments (medications, surgery, education, etc.) in specific circumstances

Complex mixture A mixture that is a combination of many chemicals, has a commonly known generic name, and is naturally occurring; a fraction of a naturally occurring mixture that results from a separation process; or a modification of a naturally occurring mixture or a modification of

a fraction of a naturally occurring mixture that results from a chemical modification process

Confounder A factor that is associated with both the exposure and outcome of interest and can distort the apparent magnitude or direction of the studied effect

Congener One of two or more compounds of the same kind with respect to classification

Correlation coefficient A measure of the extent to which two variables are related

Cortical Relating to the outer portion of an organ

Crustaceans Aquatic arthropods characteristically having a segmented body, a chitinous exoskeleton, and paired, jointed limbs; includes lobsters, crabs, shrimps, and barnacles

Cytokines Hormone-like proteins which regulate the intensity and duration of immune responses and are involved in cell-to-cell communication

De novo Anew; often applied to particular biochemical pathways in which metabolites are newly biosynthesized

Dioxins and dioxin-like compounds Unintentional contaminants that are released into the environment from combustion processes and accumulate, through the food chain, in the lipid component of animal foods

Disappearance model The total supply of imported and landed food converted to edible weight, subtracting exports, nonfood uses, and other decreases in supply, adding imports, and then dividing by the total population to estimate per capita consumption

Dose-response relationship A relationship between the amount of an agent (either administered, absorbed, or believed to be effective) and changes in certain aspects of the biological system, apparently in response to the agent

Dysarthria A disturbance of speech and language

Effect modifier Variation(s) in the association between an exposure and outcome occurring across different strata of a third variable (e.g., the association between oral contraceptive use and myocardial infarction differs between smokers and nonsmokers)

Efficacy measurement endpoint Measure of an intervention's influence on a disease or health condition

Epidemiology The study of the distribution and determinants of health-related states and events in populations and the control of health problems

Erythrocyte A mature red blood cell

Essential fatty acids Fatty acids that cannot be synthesized by the body and therefore must be included in the diet (e.g., ALA)

Etiology Cause and origin of a disease

Experimental trials A type of study in which human or animal exposure to a substance occurs in a controlled environment for the purpose of studying its effects; in humans, experimental trials are only ethical when there is equipoise between the two arms of the trial

Fate and transport Models used by risk assessors to estimate the movement and chemical alteration of contaminants as they move through the environment (e.g., air, soil, water, groundwater)

Fibrinogen A protein in blood plasma that is essential for the coagulation of blood

Filter-feeding animal An aquatic animal, such as a clam, barnacle, or sponge, that feeds by filtering particulate organic material from water

First Nation An organized aboriginal group or community, especially any of the bands officially recognized by the Canadian government

Flora The microorganisms that normally inhabit a bodily organ or part

Food frequency questionnaire (FFQ) A method of collecting food consumption data; a self-administered questionnaire that asks a study participant how often he/she consumed, on average, a list of specific foods in the past weeks, months, or years to determine a usual long-term diet

Functional foods Foods or dietary components that may provide a health benefit beyond basic nutrition

Genotoxin A toxin (poisonous substance) that harms the body by damaging DNA molecules

Geometric mean A measure of central tendency by which all N terms are multiplied together and the Nth root extracted; useful for summarizing highly skewed data and ratios

Global (in the sense of study) Involving the whole population

Grating stimuli A geometric pattern used as a substitute for letters or symbols in tests of visual acuity in infants

Half-life The time required for the elimination of half a total dose from the body

Hazard ratio (HR) Broadly equivalent to relative risk (RR); applying information collected at different times, it is useful when the risk is not constant with respect to time; the term is typically used in the context of survival over time; if the HR is 0.5, then the relative risk of death for one group is half the risk of death in the other group

Health Professionals Follow-up Study A study initiated in 1986 and conducted by researchers at the Harvard School of Public Health; enrolled 51,529 male health professionals (dentists, pharmacists, optometrists, osteopath physicians, podiatrists, and veterinarians), aged 40–75, to evaluate the relationship between nutritional factors and the incidence of serious illnesses such as cancer, heart disease, and other vascular diseases in men; follow-up questionnaires were mailed out every two years to

update exposure information and identify cases; designed to complement the all-female Nurses' Health Study (see below)

Health risk appraisal (HRA) An instrument commonly used in worksite preventive health care to identify the likelihood that an individual will develop a preventable or chronic disease, based on personal, medical, and lifestyle indications; comprises a questionnaire, risk estimation, and educational information

Histamine A hormone/chemical transmitter involved in local immune responses, regulating stomach acid production, and in allergic reactions as a mediator of immediate hypersensitivity; has been implicated in seafood toxicants from certain species of fish exposed to thermal abuse

Homeostasis The state of equilibrium in the body with respect to various functions and to the chemical compositions of the fluids and tissues

Hot spots Localized areas with high pollutant concentrations

Immunoglobulin A (IgA) The class of antibodies produced predominantly against ingested antigens, found in body secretions such as saliva, sweat, or tears, and functioning to prevent attachment of viruses and bacteria to epithelial surfaces

In vitro In an artificial environment outside the living organism

Intima-media thickness A unique diagnostic and monitoring service to determine the presence of coronary atherosclerosis in its early stages; refers to a measurement of the first two layers of the artery (intima and media)

Intrauterine growth retardation A condition resulting in a fetal weight less than the 10th percentile of predicted weight for gestational age

Inuit A general term for a group of culturally similar indigenous peoples inhabiting the Arctic coasts of Siberia, Alaska, the Northwest Territories, Nunavut, Québec, Labrador, and Greenland

Lean meat equivalent Amounts of meat alternatives that count as equivalent to 1 ounce of cooked lean meat, e.g., 1/2 cup of cooked dry beans or peas, 1/2 cup tofu, 2 tablespoons of peanut butter, 1/3 cup of nuts, or 1/4 cup of seeds

Leukocyte White blood cell; blood cells that engulf and digest bacteria and fungi; an important part of the body's defense system

Linear model Fitting a straight line to the data to help describe a pattern in the data; the term "linear" refers to the fitted straight line, and the term "model" refers to the equation that summarizes the fitted line

Lipids Members of a large group of organic compounds insoluble in water and soluble in fat solvents; lipids of nutritional importance include essential fatty acids, triglycerides, and sterols

Lipophilic compounds Substances capable of dissolving, of being dissolved in, or of absorbing lipids; lipid soluble

Lipoprotein A compound protein consisting of protein and lipid; has the solubility characteristics of protein and hence is involved in lipid transport

High-density lipoprotein (HDL) A complex of lipids and proteins in approximately equal amounts that functions as a transporter of cholesterol in the blood; high levels are associated with a decreased risk of atherosclerosis and coronary heart disease

Low-density lipoprotein (LDL) A lipoprotein that transports cholesterol in the blood; composed of a moderate amount of protein and a large amount of lipid; high levels are thought to be associated with increased risk of atherosclerosis and coronary heart disease

Listeria monocytogenes A principal pathogenic bacterium that has been associated with safety risk from a large variety of foods, including seafoods

Lipoprotein (a) [Lp(a)] An LDL-like particle that is produced in the liver; numerous studies have found that concentrations of plasma Lp(a) above 0.3 g/L (note reference ranges may vary between laboratories) are associated with an increased risk of coronary heart disease

Maximum likelihood A popular statistical method used to make inferences about parameters of the underlying probability distribution of a given dataset

Mechanistic Of or relating to the philosophy of mechanism, especially tending to explain phenomena only by reference to physical or biological causes

Meta-analysis Combined results of several studies that address a set of related research hypotheses

Metaphase A stage of mitosis; condensed chromosomes, carrying genetic information, align in the middle of the cell before being separated into each of the two daughter cells

Methylmercury The form of mercury of greatest concern with regard to seafood consumption; results when mercury from other forms is deposited in bodies of water and biotransformed through the process of methylation by microorganisms; it bioaccumulates through the food chain, and thus its highest concentrations are in large long-lived predatory species

Minimal risk level An estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure

Mitotic Of or relating to mitosis, the process by which a cell separates its duplicated genome into two identical halves

Molar A unit of concentration for solutions

Molluscan Of or relating to numerous chiefly marine invertebrates, typically having a soft unsegmented body, a mantle, and a protective calcareous shell; includes edible shellfish and snails

Monte Carlo analysis Randomly generates values for uncertain variables over and over to simulate a model

Muktuk The skin and underlying fat (blubber) layer of a whale

Multicenter A single study conducted in more than one location

Multipliers Quantifies the additional effects of an exposure/intervention beyond those that are immediately attributable to the intervention alone

Multivariate analysis A method in which several dependent variables can be considered simultaneously; not to be confused with multivariable analysis that involves several variables, even if only one dependent variable is considered at a time

Myocardial infarction Sudden insufficiency of arterial or venous blood supply involving the middle layer of the heart usually as a result of a closed, or closing, coronary artery

Myometrium The muscular wall of the uterus

MyPyramid Released in 2005 by the US Department of Agriculture (USDA) to help consumers make choices from every food group, find their balance between food intake and physical activity, and get the most nutrition out of their calories; replaced the Food Guide Pyramid; can be found at http://www.mypyramid.gov

Norovirus A group of related, single-stranded RNA, nonenveloped viruses that cause acute gastroenteritis in humans; transmitted primarily through the fecal-oral route, either by consumption of fecally contaminated food or water, or by direct person-to-person spread

Northern dwellers Native people living in the far north

Nunavik The arctic region of Québec, Canada; an Inuit homeland

Nurses' Health Study A study initiated in 1976 and conducted by researchers at the Channing Lab, Harvard Medical School and the Departments of Epidemiology and Nutrition, Harvard School of Public Health; enrolled 121,700 female registered nurses aged 30–55 living in 11 states to assess risk factors for cardiovascular disease and cancer; follow-up questionnaires were mailed out every two years to update exposure information and identify cases and, as of 1980, included a diet assessment

Observational studies Study types that follow a population (either prospectively or retrospectively) to examine how exposure to risk factors influences one's probability of developing a disease in the absence of intervention; includes cross-sectional studies, cohort studies, and case-control studies

Occipital cortex The part of the brain used to process visual information

Odds ratio (OR) In a case-control study (see above), the exposure odds among cases compared to the exposure odds among controls, where the exposure odds are the number of individuals with the exposure relative to the number of individuals without the exposure (e.g., if 3 out of 10 people are exposed, then the exposure odds are 3:7)

Omega-3 fatty acids (n-3 fatty acids) Polyunsaturated fatty acids found in oil from fatty fish as well as plant sources; characterized by the presence of a double bond 3 carbons from the methyl end in the carbon chain; includes alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA)

Omega-6 fatty acids (n-6 fatty acids) Polyunsaturated fatty acids found in animal and vegetable sources of fat; characterized by the presence of a double bond 6 carbons from the methyl end in the carbon chain; includes linoleic acid (LA) and arachidonic acid (AA)

One component pharmacokinetic model Assumes that the drug in question is evenly distributed throughout the body into a single compartment and that the rate of elimination is proportional to the amount of drug in the body; only appropriate for drugs which rapidly and readily distribute between the plasma and other body tissues

P-value As in hypothesis testing; the probability of getting a value of the test statistics as extreme as, or more extreme than, the value observed, if the null hypothesis (i.e., no association, no effect of treatment) were true; the alternative hypothesis determines the direction of "extreme"; usually $p<0.05$ means that the null hypothesis is rejected and the association between the exposure and outcome is statistically significant

Parenteral The introduction of substances into an organism by intravenous, subcutaneous, intramuscular, or intramedullary injection

Paresthesia A skin sensation, such as burning, prickling, itching, or tingling, with no apparent physical cause

Pathogenic bacteria Bacteria that cause disease or abnormality

Pelagic fish Fish living in open oceans or seas rather than waters adjacent to land or inland waters

Persistent organic pollutants (POPs) Organic chemicals that remain intact in the environment for long periods, become widely distributed geographically, bioaccumulate up the food chain by accumulating in fatty tissues of animals, and pose a risk of causing adverse effects to human health and to the environment

Plasma lipids Lipids in the fluid portion of anticoagulated blood

Platelet A type of blood cell that helps prevent bleeding by causing blood clots

Population attributable risk The proportion of disease in a population that would be prevented if the risk factor were removed from the entire population

Post hoc Formulated after the fact; for example, a post hoc analysis is designed and applied to data already collected for another study

Precentral gyrus The convolution of the frontal lobe of the brain that is bounded in back by the central sulcus and that contains the motor area

Preeclampsia A toxic condition developing in late pregnancy characterized by a sudden rise in blood pressure

Prophylactic Preventing disease

Prospective cohort study An epidemiological and observational study in which a defined group of persons known to be exposed to a potential disease risk factor is followed over time and compared to a group of persons who were not known to be exposed to the potential risk factor, to evaluate the differences in rates of the outcome; also termed a prospective observational study, follow-up study, incidence study

Prostaglandins Lipid-based membrane-associated chemical messengers synthesized by most tissue cells; act locally as a hormone-like substance; may be synthesized from both omega-3 and omega-6 fatty acids

Provisional tolerable weekly intake Exposure limit presented in micrograms of contaminant per week and per 1 kg body mass

Public Health Service Act Defines the federal agencies and their personnel who are are part of the federal Public Health Service

Reference Dose (RfD) An estimate (with uncertainty spanning perhaps an order of magnitude) of daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime

Regression coefficient The slope of the straight line that most closely relates two correlated variables; the number of units that a dependent variable changes for each one unit increase in an independent variable

Relative risk (RR) Rate of the outcome of interest in a population compared with the rate in the reference population

Risk assessment An organized process used to describe and estimate the likelihood of adverse health outcomes from environmental exposures to chemicals; the four steps are hazard identification, dose-response assessment, exposure assessment, and risk characterization

***Salmonella* spp.** A genus of bacteria including several pathogenic species that have been associated with risk from contaminated foods, including seafoods

Saturated fat Fatty acids with no double bonds; fats that are solid enough to hold their shape at room temperature (about 70°F)

Science-based knowledge Conclusions (findings and recommendations) based on clear and consistent evidence from both observational and experimental study designs

Scombroid poisoning Intoxication by foods that contain high levels of histamine caused by bacterial contamination

Serum lipids Lipids in the fluid portion of coagulated blood

Shellfish Common terminology used to identify crustacean and/or molluscan seafoods

Standard deviation A statistic that shows how tightly all the various data points are clustered around the mean in a set of data

Tertile A contiguous grouping (low, middle, high) of one-third of a sample or population

Thermal abuse Improper refrigeration or heat exposure during preparation, storage, or transfer

Toxicant Any substance or material that can injure living organisms through physicochemical interactions

Toxicity equivalency factor A numerical index that is used to compare the toxicity of different congeners and substances

Toxicokinetic The processes of absorption, distribution, metabolism, and excretion that occur between the time a toxic chemical enters the body and when it leaves

Toxin A poisonous substance (of animal, mineral, vegetable, or microbial origin) that can cause damage to living tissues

Trophic Of or relating to nutrition

Triglycerides (TG) A naturally occurring ester of three fatty acids and glycerol that is the chief constituent of fats and oils

Uncertainty factor (UF) One of several (generally 10-fold factors) used in operationally deriving the Reference Dose (RfD) from experimental data. UFs are intended to account for (1) the variation in sensitivity among members of the human population; (2) the uncertainty in extrapolating animal data to the case of humans; (3) the uncertainty in extrapolating from data obtained in a study that is of less-than-lifetime exposure; and (4) the uncertainty in using Lowest Observed Adverse Effect Level data rather than No Observed Adverse Effect Level data

Value trade-off The willingness to pay a higher price for something with a higher value rating attached

Vibrio vulnificus A bacterium usually associated with raw molluscan shellfish

Voluntary Seafood Inspection Program A program for inspection and certification of seafood processing plants, designed to ensure quality more than product safety; conducted by the National Marine Fisheries Service

SUPPLEMENTARY INFORMATION ON NUTRIENTS OF SPECIAL INTEREST IN SEAFOOD

Omega-3 Fatty Acids

Omega-3 fatty acids occur widely throughout the plant and animal kingdoms. Algae, fungi, bacteria, insects, and some vertebrates possess the array of enzymes needed for de novo synthesis of these fatty acids (Gill and Valivety, 1997a). Genetically complex plants, though they may be good

sources of alpha-linolenic acid (ALA), rarely produce polyunsaturated fatty acids longer than 18 carbons and thus are not sources of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Though more genetically complex animals can synthesize EPA and DHA from ALA (Qiu, 2003), the rate of synthesis in most species is low. Fish are good sources of EPA and DHA primarily because their natural diets contain these fatty acids, not because they are able to synthesize them de novo. Organisms low on the food chain consume the algal and microbial sources of EPA and DHA, which become concentrated in the lipid stores of those species higher up in the food chain.

Derivation of the Omega-3 Fatty Acids

Omega-3 fatty acids are long-chain polyunsaturated fatty acids that are characterized by the presence of a double bond at the omega position (3 carbon atoms from the methyl end) in the carbon chain. This position is what identifies them as omega-3 fatty acids. EPA and DHA are not endogenously synthesized from saturated, monounsaturated, or omega-6 fatty acids; they can only be made from the precursor omega-3 fatty acid, ALA. Figure A-1 shows the synthesis pathways for omega-3 fatty acids.

The omega-3 fatty acids include:

- Alpha-linolenic acid, 18:3 n-3, a plant-derived source of fatty acid. ALA can be converted to the omega-3 fatty acids EPA and DHA through a series of desaturation and chain elongation events, but the conversion in humans is inefficient and varies with the content of other fatty acids in the diet (see discussion below for more information about conversion efficiency);
- Eicosapentaenoic acid, 20:5 n-3, a fatty acid synthesized from ALA and found primarily in fatty fish. EPA is a precursor molecule in the human synthesis of one family of eicosanoids, including prostaglandins, thromboxane, leukotrienes, hydroxy fatty acids, and lipoxins. These compounds serve as modulators of cardiovascular, pulmonary, immune, reproductive, and secretory functions at the cellular level;
- Docosahexaenoic acid, 22:6 n-3, a fatty acid synthesized from ALA and found primarily in fatty fish. It is a component of all membrane structural lipids in neural and retinal tissues and spermatozoa. The developing brain accumulates large amounts of DHA late in fetal life. This accumulation continues through at least the first 2 postnatal years.

Selenium

Selenium is an element classified within Group VIA in the periodic table following oxygen and sulfur but preceding tellurium and polonium.

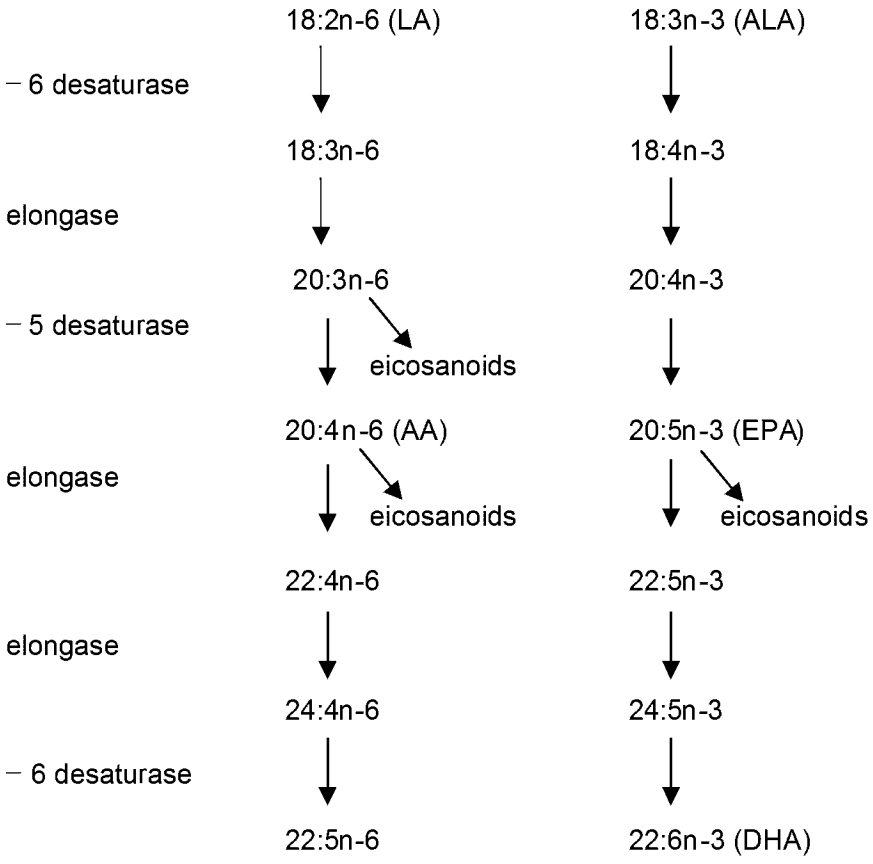

FIGURE A-1 Biosynthesis of long-chain fatty acids.
NOTES: LA = Linoleic acid; AA = Arachidonic acid; ALA = Alpha-linolenic acid; EPA = Eicosapentaenoic acid; DPA = Docosapentaenoic acid; DHA = Docosahexaenoic acid.
SOURCE: Derived from IOM, 2002/2005.

This position in the periodic table leads to the classification of selenium as a metalloid element with unique chemistry and biochemistry, i.e., exhibiting both metallic and nonmetallic properties. Selenium can form bonds with other selenium atoms, a characteristic referred to as catenation and shared with other elements like carbon, silicon, and sulfur. Elemental selenium is found in three forms: the gray-black form or metallic hexagonal selenium, an amorphous white form, and a monoclinic red form. Selenium has six electrons in the 4s and 4p, orbital and the empty d [illegible] bonds of selenium, like sulfur, can be filled by [illegible] electrons of oxygen. Selenium and sulfur have

similar radii Δ, 1.03 and 1.07 (covalent radii), and similar electronegativities of 2.44 and 2.48, respectively. Thus, the chemical reactivity of selenium and sulfur are similar. However, the reduction potential of selenous and selenic acids are much greater than those of the analogous sulfur acids so that when both are in the same mixture, selenite will be reduced to elemental selenium but sulfite will be oxidized to sulfate.

Selenium Essentiality

Selenium occurs in all the cells and tissues of mammalian species and reflects the level of dietary selenium over a wide range of intakes. Selenium was recognized as an essential nutrient when Schwarz and Foltz (1957) showed that a form of liver necrosis developed in rats if either vitamin E or selenium was excluded from their diet. It is now recognized that both selenium and vitamin E have important roles in the detoxification of hydroperoxides and free radical byproducts (Sunde, 2001).

Selenium deficiency has been demonstrated in premature infants and patients utilizing long-term selenium-free enteral or parenteral solutions. Deficiency symptoms include red blood cell hemolysis, cardiomyopathy, growth retardation, cataract formation, abnormal placenta retention, lack of spermatogenesis, and skeletal muscle degeneration. There is a decline of selenoproteins, particularly glutathione peroxidase activity. Selenium deficiency has been found to be endemic in regions of China, where it is called Keshan disease. Children are particularly susceptible, and the disease is characterized by cardiomyopathy. Selenite-enriched salt has been shown to assist in the reversal of this deficiency, but it is likely that selenium is only one factor. Coxsackie virus has been isolated from persons with Keshan disease, and recent animal research has provided evidence that viral infections may be influenced by selenium status. The Institute of Medicine has recommended an intake of no less than 55 and no more than 400 ∝g of selenium per day as sufficient to meet the needs of the average adult (IOM, 2000).

Selenium is an essential element in a group of proteins, i.e., selenoproteins. Sulfur amino acids and selenium are involved in the synthesis of these selenoproteins via selenophosphate to form selenocysteine, catalyzed by the enzyme selenophosphate synthetase. Approximately 25 selenoproteins have been identified, with half characterized with respect to their function (Kryukov et al., 2003). Of those characterized for function, over half perform free radical detoxification. The list of established selenoproteins and their respective biological functions are listed in Table A-1 (Sunde, 2000). The selenium is incorporated into the peptide backbone of selenium-containing proteins as selenocysteine. Novel metabolic pathways are necessary to convert various dietary forms of selenium into the selenocysteine entity. Dietary selenate and selenite are reductively converted to selenide,

TABLE A-1 Selenoproteins and Biological Functions

Selenoproteins	Function
Cytosolic glutathione peroxidase, GPX1	Major form of selenium, protects against hydroperoxides
Phospholipid hydroperoxide glutathione peroxidase, GPX4	Lipophilic, works within membranes to destroy peroxides
Gastrointestinal glutathione peroxidase, GPX2	Protect intestine against external peroxides
Extracellular glutathione peroxidase, plasma GPX, GPX3	Secreted GPX, major form of selenium in milk
Selenoprotein W, SELW	Small 9.8 kDa selenoprotein found in muscle, postulated to have antioxidant function
Selenoprotein P, SELP	Major plasma selenoprotein, postulated to protect the cardiovascular system against oxidant damage
Thioredoxin reductase, TRRs	Reduce small intracellular molecules, regulate intracellular redox state, and may have important roles in antioxidant defense
Iodothyronine deiodinase	Activation and metabolism of thyroid hormone
Sperm capsule selenoprotein	

SOURCE: Derived from Sunde, 2001.

usually in the intestinal or erythrocyte cells. Selenium released from selenomethionine breakdown will also enter this pool as selenide. Subsequently, synthesis of selenocysteine involves several unique intermediates but it is the selenide that serves as the precursor to selenocysteine.

Selenium Food Sources

Plant and animal levels of selenium vary widely, reflecting the wide range of selenium content of soils (Sunde, 2001). Corn, rice, and soybeans grown in a selenium-poor region of China contain 0.0005, 0.007, and 0.010 ∝g/g, respectively, while those grown in seleniferous areas of China can have a selenium content as high as 8.1, 4.0, and 11.9 ∝g/g, respectively. Organ meats and seafood are usually good sources for this element (USDA, 2005), with levels ranging from 0.4 to 1.5 ∝g/g, whereas levels in muscle meats

range from 0.1 to 0.4 ∝g/g, and in dairy products, less than 0.1 to 0.3 ∝g/g. Drinking water usually has a negligible selenium content, unless it comes from well waters in seleniferous areas (Sunde, 2001).

Selenium Toxicity

Berzelius first reported the existence of selenium as a metal in 1817. In nature, selenium is often found in combination with lead, copper, mercury, and silver as selenides, similar to sulfur counterparts. Localized seleniferous areas can be found in various parts of the Great Plains in North America. Seleniferous areas also have been identified in Ireland, Israel, Australia, Russia, and South Africa. In grazing livestock of North America, the dis - ease associated with excess selenium intake is known as alkali disease or blind staggers. Selenium accumulator plants ingested by livestock are often the source of selenosis or selenium poisoning. Selenium poisoning can be a mild chronic condition, or severely acute, resulting in death. Acute selenium poisoning resulting in death is often preceded by blindness, abdominal pain, salivation, grinding of the teeth, and paralysis. Death is usually due to respiratory failure, which is often complicated by starvation resulting from loss of appetite, marked restriction of food intake, anemia, and severe pathological changes in the liver (Hogberg and Alexander, 1986). Dullness and lack of vitality, emaciation and roughness of coat, loss of hair, erosion of the joints, atrophy of the heart and cirrhosis of the liver, and anemia characterize chronic selenium poisoning. Chronic selenium poisoning can occur in rats and dogs given diets containing 5–10 ppm selenium. It is likely that the minimum toxic level is 4–5 ppm selenium. Acute toxicity in humans occurs when selenium intake is in excess of 750 ∝g/day. Usually toxicity occurs when individuals are exposed to high dietary intake and industrial conditions (smelters) that increase the body burden of selenium.

The precise ways in which selenium at toxic intakes exerts toxicity are not completely understood. Inhibition of oxygen consumption by tissues appears to be mediated through a poisoning of succinic dehydrogenase.

When selenium intake is high, it can be methylated through S-adenosyl- methione by either microsomal or cytosolic methyltransferases, forming the products methyl, dimethyl, trimethyl derivatives. Dimethyl selenide is the volatile seleno derivative giving the garlic-like odor (Sunde, 2001).

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B

Data Tables

Note: Abbreviations/acronyms included in the following data tables are included in the Glossary (see Appendix A).

Studies on Women, Infants, and Children

TABLE B-1a Studies on Preeclampsia: Effects on Women Who Increase Seafood and/or Omega-3 Fatty Acid Intake

Author	Study Type	Subjects	Exposure	Timing of Exposure
Sibai, 1998	Review	3 randomized controlled trials	Fish-oil supplement	
Sindelar et al., 2004	Randomized Controlled Trial	Men (n=8) Women (n=4) Mean age of 33 years Lincoln, NE Non-Hispanic White Recruited at YMCA marathon and triathlon training group meetings and word of mouth Exercising regularly as members of a running training group sponsored by the local YMCA No being treated with eating disorders or depression, or those unable to eat eggs, or those using medications known to affect serum lipids	n-3 PUFA-enriched eggs	2 weeks baseline period, 4 weeks treatment period (crossover design), 4 weeks washout period between treatments
Haugen and Helland, 2001	Randomized Controlled Trial	Pregnant women (n=37) Mean age about 27-31 years Oslo, Norway Normotensive without proteinuria, had uncomplicated term pregnancies, randomly taken from another study investigating the influence of omega-3 fatty acids on fetal, neonatal, and child development Another group had moderate preeclampsia	Cod-liver oil supplement	16-20 weeks gestation through pregnancy

Amount	Results	Conclusion*
	"The beneficial effects of fish oil on the incidence of preeclampsia are supported by observational studies and 1 large, uncontrolled early trial." Three randomized trials "reveal no reduction in the incidence of preeclampsia in the fish oil group."	N
n-3 PUFA-enriched eggs: flaxseed added to hens' diet 350 mg n-3 PUFA/60 g egg 0.25 g LA, 0.10 g DHA/60 g egg 1 egg/day for 6 days and no eggs on day 7 Conventional eggs: 60 mg of n-3 PUFA/60 g egg 0.04 g LA, 0.02 g DHA/60 g egg 1 egg/day for 6 days and no eggs on day 7	LA, DHA, and total n-3 dietary intake of those randomized to n-3 PUFA-enriched egg treatment were significantly higher than at baseline and compared to the conventional egg treatment ($p<0.05$). There were no significant differences in serum total cholesterol, LDL-C and HDL-C in physically active adults from baseline to end of treatment or between groups. Serum triglycerides were significantly higher with n-3 PUFA-enriched egg treatment than those from baseline and compared to the conventional egg treatment ($p<0.05$).	N/A
Cod-liver oil group: 10 mL/day Corn oil group: 10 mL/day	"The pressure increase was significant in both groups, but no significant differences in the constrictory response or in the proportions of preparations displaying dilatatory responses were observed when compared to appropriate control groups." "Neither preeclampsia nor dietary supplementation with cod-liver oil had any significant effect on the vasoactive response to PGF2± in umbilical cord arteries."	N

continued

TABLE B-1a Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Salvig et al., 1996	Randomized Controlled Trial	Pregnant women (n=533) Aged 18-44 years Aarhus, Denmark No history of placental abruption in an earlier pregnancy or a serious bleeding episode in the present pregnancy, no prostaglandin inhibitors regularly, no allergy to fish and regular intake of fish oil	Fish-oil supplement	30th week gestation through pregnancy
Onwude et al., 1995	Randomized Controlled Trial	Pregnant women (n=233) Aged 18-39 years for fish oil group Aged 16-40 for placebo group Leeds, UK Multigravida with a history of one or more small babies, a history of proteinuric or nonproteinuric pregnancy-induced hypertension, or a history of unexplained stillbirth Primigravida with abnormal uterine arcuate artery Doppler blood flow at 24 weeks gestation	EPA/DHA supplement	Until 38th week gestation; enrollment time unspecified
Bulstra-Ramakers, 1995	Randomized Controlled Trial	Pregnant women (n=63) Groningen, Netherlands Birth weight below the 10th percentile in association with pregnancy-induced hypertension or chronic renal disease, or with placenta abnormalities	EPA supplement	12-14 weeks gestation until delivery

Amount	Results	Conclusion*
Fish oil group: 2.7 g/day (4 capsules/day, each capsule contains 32% EPA, 23% DHA, 2 mg tocopherol/ml) Olive oil group: 1 g; 72% oleic acid and 12% LA/capsule 4 capsules/day Control = no capsule	"Mean blood pressure increased during the course of the 3rd trimester," but this change was not statistically different among the three groups. "No differences were seen between the groups in proportions of women with a systolic blood pressure above 140 mmHg or a systolic blood pressure above 90 mmHg, although the proportion of women with diastolic above 90 mmHg tended to be lower in the fish oil group compared to the olive oil group (RR=0.48, p=0.07)."	N
2.7 g/day (1.62 g/day of EPA) (1.08 g/day of DHA)	There were no significant differences between the two groups for proteinuric pregnancy-induced hypertension, nonproteinuric pregnancy-induced hypertension, birth weight, gestation length, perinatal death, duration of labor, onset of labor (spontaneous, induced, or prelabor section), or mode of delivery.	N
4 capsules 3 times/day (each capsule contains 0.25 mg EPA) vs. placebo	"Addition of 3 g/day of EPA to the diet did not result in either a lowering of the incidence of pregnancy induced hypertension or intrauterine growth retardation." "Birth weight centiles were slightly lower and the recurrence rate of pregnancy-induced hypertension was slightly higher in the EPA group," compared to the control group, although these differences were not significant.	N

continued

TABLE B-1a Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Schiff et al., 1993	Controlled Trial	Pregnant women (n=16) Aged 25-34 years Nulliparous Nonsmokers, no history of hypertension, coagulation disorders, thrombocytopenia, or chronic vascular, renal, or other disease	Fish-oil supplement	32-34 weeks through the next 21 days
Olsen and Secher, 1990	Randomized Controlled Trial	Pregnant women (n=5022) Aged 15-44 years London People's League of Health, 1946 Attending antenatal clinics of 10 hospitals No disease or physical abnormality	EPA/DHA supplement	Enrolled at <24 weeks gestation; treatment lasts for <15 weeks (n=288), 16-19 weeks (n=411), 20-23 weeks (n=414), or 24+ weeks (n=417)

Amount	Results	Conclusion*
6 capsules/day (each capsule contains 1000 mg of concentrated fish oil, 26% of which is n-3 fatty acids)	"Mean excretion of 11-dehydro-thromboxane B_2 before and after 21 days of fish oil consumption was reduced among the fish oil-treated women from 1606±411 pg/mg of creatinine to 779±299 pg/mg after treatment ($p<0.0001$, paired t test). In all 11 patients the decreased excretion of this metabolite was considerable, ranging from 32% to 71%." No significant change was detected among the control women.	B
0.1 g/day of EPA+DHA from halibut oil in supplement vs. no supplement Supplement includes 0.26 g ferrous iron; 0.26 g calcium; minute quantities of iodine, manganese and copper; 0.60 g thiamin/g; 0.10 g vitamin C; 0.36 g halibut liver oil	In primiparae, the OR for preeclampsia was significant when comparing the treatment to the control group (OR=0.689, 95% CI 0.50-0.95). In primiparae, the OR for albuminuria was statistically significant when comparing the treatment to the control group (OR=0.717, 95% CI 0.54-0.96). In primiparae, the OR for hypertension was not significant when comparing the treatment to the control group (OR=0.862, 95% CI 0.73-1.02). In multiparae, these statistics were OR=0.677 (95% CI 0.43-1.07), OR=0.675 (95% CI 0.44-1.04), and OR=1.121 (95% CI 0.89-1.42). There were no significant effects on the occurrences of stillbirths, early neonatal deaths (before 8 days), perinatal deaths, sepsis, or the duration of labor.	B

continued

TABLE B-1a Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Clausen et al., 2001	Cohort	Pregnant women (n=3133) Mean age 29.8 years 51.8% nulliparous Representing all socioeconomic classes Aker University Hospital, Oslo, Norway No pregestational diabetes or twin/triplet pregnancies	Fatty acids from food	17-19 weeks gestation until after delivery

Amount	Results	Conclusion*
Tertiles of saturated fatty acids (%energy) Mean = δ12.0, 12.0-15.0, >15.0 Tertiles of monounsaturated fatty acids (%energy) Mean = δ10.5, 10.5-13.0, >13.0 Tertiles of polyunsaturated fatty acids (%energy) Mean = δ5.2, 5.2-7.5, >7.5 Tertiles of omega-3 fatty acids (%energy) Mean = δ0.9, 0.9-1.6, >1.6 Tertiles of omega-6 fatty acids (%energy) Mean = δ3.8, 3.8-5.8, >5.8	After adjusting for energy, age, smoking, BMI, systolic blood pressure for 20 weeks' gestation, nullipara and energy: Statistically significant ORs for preeclampsia, comparing the highest group to the lowest group of fatty acid intakes, were observed for polyunsaturated fatty acids (p=0.01) and omega-6 fatty acids (p=0.05); and Statistically nonsignificant ORs for preeclampsia, comparing the highest group to the lowest group of fatty acid intakes, were observed for saturated fat (p=0.10), monounsaturated fat (p=0.59), and omega-3 fatty acids (p=0.06).	N

continued

TABLE B-1a Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Velzing-Aarts et al., 1999	Case-control	Cases (n=27) = preeclamptic women Controls (n=24) = normotensive, nonproteinuric women Pregnant women Mean age about 27 years Curacao	Fatty acid composition in maternal and umbilical platelets and umbilical arteries and veins	During delivery or within 2 hours after birth

Amount	Results	Conclusion*
Mean fatty acid composition in maternal platelets (in mol%): Controls = 9.66±2.75 LA; 0.27±0.10 ALA; 0.29±0.14 EPA; 2.03±0.62 DHA Cases = 7.02±1.91 LA; 0.22±0.11 ALA; 0.21±0.07 EPA; 2.16±0.93 DHA	"Newborns of preeclamptic women had significantly lower birth weights and gestational ages at delivery," compared to newborns of non-preeclamptic women. Preeclamptic women had significantly lower maternal platelet levels of LA ($p<0.001$) and EPA ($p<0.05$) compared to normotensive women.	B
Mean fatty acid composition in umbilical cord platelets (in mol%): Controls = 3.73±0.76 LA; 0.14±0.10 ALA; 0.16±0.07 EPA; 2.33±0.58 DHA Cases = 4.16±1.51 LA; 0.21±0.11 ALA; 0.17±0.07 EPA; 1.97±0.30 DHA	Preeclamptic women had significantly lower umbilical arteries levels of EPA ($p<0.01$) and DHA ($p<0.001$) compared to normotensive women. No other significant differences were found for LA, ALA, EPA, or DHA.	
Mean fatty acid composition in umbilical veins (in mol%): Controls = 2.69±0.44 LA; 0.10±0.05 ALA; 0.09±0.04 EPA; 4.26±0.85 DHA Cases = 2.89±0.56 LA; 0.11±0.05 ALA; 0.07±0.02 EPA; 3.35±0.96 DHA		
Mean fatty acid composition in umbilical arteries (in mol%): Controls = 1.87±0.39 LA; 0.10±0.04 ALA; 0.09±0.03 EPA; 4.83±0.76 DHA Cases = 1.74±0.75 LA; 0.10±0.06 ALA; 0.06±0.03 EPA; 3.73±1.03 DHA		

continued

TABLE B-1a Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Kesmodel et al., 1997	Nested case-control	Cases = women with preeclampsia (n=43), pregnancy-induced hypertension (n=179), intrauterine growth retardation (n=182), delivering preterm (n=153), delivering postterm (n=189) Control = sample from whole cohort (n=256) Pregnant women Aarhus, Denmark	Seafood and fish-oil supplement	Between 6 months and 3 1/2 years after delivery
Williams et al., 1995	Case-control	Cases (n=22) = preeclamptic Controls (n=40) = normotensive Pregnant women Mean age 28.6-31.2 years White (n=17 in preeclamptic group, n=23 in non-preeclamptic group) Seattle, Washington About 21% Medicaid recipient	Maternal erythrocytes fatty acid profiles	Day after delivery

Amount	Results	Conclusion*
Low intake = Maximum of 1 fish snack/ week and 1 fish meal/month and no fish oil	After adjusting for maternal smoking habits, maternal height, maternal weight before pregnancy, parity, maternal social status, and average daily calcium intake:	N
High intake = Minimum of 4 fish snacks/ week or 4 fish meals/month or intake of fish oil during pregnancy	There were no significant ORs of pregnancy-induced hypertension, preeclampsia, intra-uterine growth retardation, preterm delivery or postterm delivery for the middle-intake group or the high-intake group compared to the low-intake group.	
Middle intake = Everyone else		
Tertiles of EPA: Median = 0.20, 0.26, 0.36	After adjusting for parity and pre-pregnancy BMI, the OR of preeclampsia for the lowest tertile of EPA, compared to the highest tertile of EPA was 5.54 (95% CI 1.06-28.79).	B
Tertiles of DPA: Median = 1.54, 1.75, 2.02	After adjusting for parity and pre-pregnancy BMI, the OR of preeclampsia for the lowest tertile of DPA, compared to the highest tertile of DPA was 3.33 (95% CI 0.65-16.99).	
Tertiles of DHA: Median = 4.38, 5.14, 6.40	After adjusting for parity and pre-pregnancy BMI, the OR of preeclampsia for the lowest tertile of DHA, compared to the highest tertile of DHA was 7.54 (95% CI 1.23-46.22).	
Tertiles of total long-chain n-3 fatty acids: Median = 6.23, 7.09, 8.50	After adjusting for parity and pre-pregnancy BMI, the OR of preeclampsia for the lowest tertile of the sum of long-chain omega-3 fatty acids, compared to the highest tertile of long-chain omega-3 fatty acids was 7.63 (95% CI 1.43-40.63).	

continued

TABLE B-1a Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Wang et al., 1991	Case-control	Cases (n=9) = preeclamptic women ControlsA (n=11) = normal pregnant women ControlsB (n=10) = nonpregnant women Aged 20-40 years Term (pregnant women) Not on oral contraceptives (nonpregnant women)	Plasma fatty acid analysis	During pregnancy

* N = Evidence of no association or no clear association; B = Evidence of a benefit; N/A = A conclusion is not available; these data are presented for background information only.

Amount	Results	Conclusion*
Nonpregnant women (mg/L±SE): 79.51±3.47 total PUFA, 60.79±2.28 LA, 10.99±1.01 AA, 1.88±0.17 ALA, 0.26±0.04 EPA, 5.58±0.60 DHA Normal pregnant women (mg/L±SE): 90.60±6.68 total PUFA, 62.93±4.69 LA, 12.81±0.87 AA, 3.68±0.99 ALA, 1.08±0.33 EPA, 10.40±0.94 DHA Preeclamptic women (mg/L±SE): 67.42±3.88 total PUFA, 45.98±2.80 LA, 11.44±1.00 AA, 1.11±0.25±ALA, 0.11±0.11 EPA, 8.94±0.69 DHA	Plasma total polyunsaturated fatty acid levels, LA, ALA, and EPA were all significantly higher in the normal pregnant women than in the preeclamptic women ($p<0.05$, $p<0.01$, $p<0.05$, $p<0.05$, respectively). EPA and DHA were significantly lower in the nonpregnant women compared to the pregnant women ($p<0.05$ and $p<0.01$, respectively). No other significant differences between the plasma polyunsaturated fatty acid levels in the three groups were found. "No statistical differences were noted in the five polyunsaturated fatty acid levels between fasting and non-fasting states in both non-pregnant and normal pregnant subjects."	B

TABLE B-1b Studies on Postpartum Depression: Effects on Women Who Increase Seafood and/or Omega-3 Fatty Acid Intake

Author	Study Type	Subjects	Exposure	Timing of Exposure
Marangell et al., 2004	Open trial	Pregnant women (n=7) Aged 31-42 years Married, Caucasian (except for one married, Hispanic) Baylor College of Medicine History of a depressive episode in the postpartum period, not suffering from a current depressive episode No psychotropic medications within 2 weeks of baseline, history of nonreponse to two or more antidepressants, serious comorbid medical or psychiatric illness, or significant risk of dangerousness to self or others	Fish-oil supplement	34-36 weeks gestation until 12 weeks postpartum
Llorente et al., 2003	Randomized Controlled Trial	Pregnant women (n=89) Aged 18-42 years No chronic medical condition, no dietary supplements other than vitamins, no smoking, who had not been pregnant >5 times Planned to breastfeed infants exclusively for at least 4 months Part of a larger cohort study on effects of DHA on breastfeeding mothers and their infants	Algae-derived triglyceride supplement	Within a week of delivery to 4 months after delivery
Hibbeln and Salem, 1995	Review	Summary of three cohorts	DHA depletion	

Amount	Results	Conclusion*
Fish oil group: 2960 mg fish oil/day 173 mg EPA and 123 mg DHA per day 10 capsules/day	Trial was terminated because of a high relapse rate observed after enrolling only seven participants.	N
Algae-derived triglyceride capsule (about 200 mg DHA/day) vs. placebo	"Repeated measures analysis of variance, with the use of data only from the women who completed the questionnaires at both baseline and 4 months, showed no difference between the two groups at any time" with regards to postpartum depression. "There were no significant differences between groups in the EPDS and SCID-CV scores, particularly in current or past episodes of depression, as detected by the SCID-CV." "There were no significant correlations between plasma phospholipid DHA content and BDI, EPDS, or SCID-CV scores." "The relative maternal depletion of DHA may be one of the complex factors leading to increased risk of depression in women of childbearing age and in postpartum periods."	N B

continued

TABLE B-1b Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Timonen et al., 2004	Cohort	Live female births (n=2968) Live male births (n=2721) Unselected, genetically homogeneous Northern Finland 1966 Birth Cohort	Seafood	Previous 6 months (during pregnancy) until 31 years of age

Amount	Results	Conclusion*
Rare eaters: δ1 time/month Regular eaters: ε1 time/week Serving size unspecified	After adjusting for body mass index, serum total cholesterol level, and socioeconomic situation, women who ate fish rarely had a higher OR for depression, compared to women who ate fish regularly. This statistic was observed by various measurements: Doctor-diagnosis: OR=1.3 (95% CI 0.9-1.9); HSCL-25 <2.01: OR=1.4 (95% CI 1.1-1.9); HSCL-25 <2.01 and doctor-diagnosis: OR=2.6 (95% CI 1.4-5.1). After adjusting for alcohol intake, smok - ing, physical inactivity, and marital status, women who ate fish rarely had a higher OR for depression, compared to women who ate fish regularly. This statistic was observed by various measurements: Doctor-diagnosis: OR=1.2 (95% CI 0.9-1.6); HSCL-25 <2.01: OR=1.4 (95% CI 1.1-1.8); HSCL-25 <2.01 and doctor-diagnosis: OR=2.4 (95% CI 1.4-4.2). Among men, none of these ORs were significant.	B

continued

TABLE B-1b Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Otto et al., 2003	Cohort	Participated in 2 earlier studies Pregnant women (n=112) Mean age around 30 years Caucasian Southern Limburg, Netherlands Fish intake <2 times/week No metabolic, cardiovascular, neurologic, renal, or psychiatric disorders No medications, except for multivitamins and iron supplements Singleton pregnancy Term delivery No blood transfusions in the perinatal period Gestational age <14 weeks at entry, Caucasian, fish consumption <2 times a week (for Study 2 only)	Venous (plasma) blood fatty acid composition	36 weeks gestation, at delivery, and 32 weeks postpartum
Otto et al., 2001	Cohort	Pregnant women (n=57) Mean age around 30 years Southern Limburg, Netherlands No metabolic, cardiovascular, neurologic, or renal disorders No medications, except multivitamins and iron supplements Singleton pregnancy Term delivery No blood transfusions in the perinatal period	Diet and venous blood fatty acid profiles	36-37 weeks gestation; 2-5 days after delivery; 1, 2, 4, 8, 16, 32, 64 weeks postpartum

Amount	Results	Conclusion*
Absolute amount not specified	No significant relationship was observed between DHA, n-6DPA, or their ratio and the EPDS scores at delivery or at 32 weeks postpartum. No statistically significant relationships between depression and fatty acid status were observed with DHA or n-6DPA, neither for the levels at delivery, nor for their postpartum changes. "The improvement of the DHA status during the postpartum period, as reflected by the increase of the DHA/n-6DPA ratio during this period, was higher in the non-depressed than in the depressed women (OR=0.90, p=0.04)." Similar results remained after adjusting for Study 1 or 2, parity, education level, maternal age at test moment, breastfeeding, smoking, and alcohol use (OR=0.88, p=0.03).	N
Absolute amount not specified	"After delivery, total fatty acids in plasma phospholipids decreased significantly over time in the lactating and nonlactating women ($p<0.0001$)." "The amounts of ALA, DHA, and total n-3 fatty acids showed significant downward trends postpartum in both groups, whereas the amounts of EPA and DPA increased significantly after delivery."	N/A

continued

TABLE B-1b Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Al et al., 1995	Cohort	Pregnant women (n=110) Aged 19-43 years Maastricht, Netherlands Caucasian Singleton pregnancy DBP <90 mmHg No metabolic, cardiovascular, neurological or renal disorder	Maternal venous and umbilical vein fatty acid profiles	10, 14, 18, 22, 26, 30, 32, 34, 36, 38, 40 weeks gestation; after delivery; 6 months after delivery
Holman, 1991	Cohort	Pregnant women (n=19) Aged 24-36 years Caucasian Normotensive, normal singleton pregnancies Mayo Clinic, Minnesota Controls (n=59) = staff and students from the University of Minnesota, aged 19-48 years	Blood fatty acid composition	36 weeks gestation, during labor, 6 weeks postpartum

Amount	Results	Conclusion*
Absolute amount not specified	"The average total amount of fatty acid (TF) in maternal venous plasma PL increased significantly ($p<0.0001$) during pregnancy, but the rise in TF became less pronounced towards the end of gestation ($p<0.0001$)." "Total fatty acids increased from 1238.11 mg/L at week 10 to 1867.84 mg/L at week 40 of gestation, and all of the fatty acid families showed a similar course." "The mean amount of total fatty acids in umbilical plasma phospholipids was substantially lower ($p<0.0001$) than all maternal values" for all fatty acid families. "In contrast to the absolute amounts of AA and DHA, the mean relative amounts of AA and DHA in umbilical plasma phospholipids were significantly ($p<0.0001$) higher than all maternal values."	N/A
Normal controls of nonpregnant women of childbearing age All in mol% ±SEM: 24.1±0.39 LA, 12.5±0.24 AA, 0.22±0.01 ALA, 0.53±0.03 EPA, 1.04±0.04 DPA, 3.71±0.14 DHA	All individual PUFA were less than normal in pregnant women at 36 weeks of pregnancy than in the nonpregnant women, where EPA was 42% of normal values. "The fatty acid profile of plasma phospholipids during labor was similar to that at 36 weeks except for the subnormal LA and ALA values became significant at $p<0.01$ and $p<0.05$, respectively, and the elevated 22:5n-6 became significant at 0.001." The fatty acid profile of plasma phospholipids for lactating women 6 weeks postpartum was similar to those during pregnancy and labor except that AA status improved, diminished ALA, and increased EPA and DPA toward normal. The fatty acid profile of plasma phospholipids for nonlactating women 6 weeks postpartum was similar to that of the lactating women, expect that abnormalities were less severe or of lower significance.	N/A

continued

TABLE B-1b Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Hibbeln, 2002	Cross-sectional	Pregnancy women (n=14,532) 23 countries 41 different studies	Seafood	During pregnancy, unspecified

*N = Evidence of no association or no clear association; B = Evidence of a benefit; N/A = A conclusion is not available; these data are presented for background information only.

Amount	Results	Conclusion*
Absolute amount not specified	"Greater apparent seafood consumption predicted DHA content of mothers' milk ($p<0.006$)" and "higher DHA content in mothers' milk predicted a lower prevalence rate of postpartum depression ($p<0.0001$)." "Higher national seafood consumption predicted lower prevalence rates of postpartum depression ($p<0.0001$)."	B

TABLE B-1c Studies on Gestation and Birth Weight: Effects on Infants of Mothers Who Increase Seafood and/or Omega-3 Fatty Acid Intake

Author	Study Type	Subjects	Exposure	Timing of Exposure
de Groot et al., 2004	Randomized Controlled Trial	Pregnant women (n=79) Mean age of 29-30 years Maternal education about 4 (on an 8-point scale) Maastricht, Heerlen, Sittard, southeastern Netherlands White origin, gestational age <14 weeks, normal health, fish consumption <2 times/week No hypertensive, metabolic, cardiovascular, renal, psychiatric, or neurologic disorder	ALA-supplemented margarine	14 weeks gestation until delivery
Smuts et al., 2003a	Randomized Controlled Trial	Pregnant women (n=73) Mainly African-American Aged 16-35 years Reachable by telephone Planned to deliver at the Regional Medical Center in Memphis, TN No more than four pregnancies	DHA-enriched egg	24-28 weeks gestation until delivery
Smuts et al., 2003b	Randomized Controlled Trial	Pregnant women (n=291) Aged 16-36 years Mainly African-descent Plan to deliver at Truman Medical Center in Kansas City, MO Able and willing to consume eggs, access to refrigeration Singleton gestation No weight >240 pounds at baseline, cancer, lupus, hepatitis, infectious disease, diabetes, gestational diabetes, elevated blood pressure at baseline	DHA-enriched egg	24-28 weeks gestation until delivery

Amount	Results	Conclusion*
Experimental group (% total fatty acids): ALA-enriched high-LA margarine 25 g margarine 45.36 LA, 14.18 ALA Control group (% total fatty acids): No ALA high-LA margarine 25 g margarine/day 55.02 LA, 0.17 ALA	Newborns in the experimental group had a significantly higher mean birth weight than those in the control group (p=0.043). No significant differences in gestational age, APGAR score, or umbilical plasma DHA concentrations in phospholipids were found between the two groups.	B (birth weight only)
High-DHA egg group: mean = 183.9±71.4 mg DHA/day ranged from 27.6 to 264.9 mg/day Ordinary egg group: mean = 35.1±13.2 mg DHA/day ranged from 0 to 36 mg/day Low egg intake group: mean = 10.8±4.0 mg DHA/day ranged from 0 to 36 mg/day	"Mean weight, length, and head circumference of infants in the high-DHA egg group were greater than in the ordinary egg group, and gestation was 5.6 days longer."	B
High-DHA egg group: mean = 133±15 mg DHA/egg ranged from 108 to 165 mg/egg Ordinary egg group: mean = 33±11 mg DHA/egg ranged from 22 to 51 mg/egg	After controlling for maternal BMI at enrollment and number of prior pregnancies, the mean difference in gestational age between the two groups was 6.0 ±2.3 days (p=0.009). After controlling for maternal BMI at enrollment and maternal race, the mean difference in birth weight between the two groups was not significant.	B (gestation only)

continued

TABLE B-1c Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Haugen and Helland, 2001	Randomized Controlled Trial	Pregnant women (n=37) Mean age about 27-31 years Oslo, Norway Normotensive without proteinuria, had uncomplicated term pregnancies, randomly taken from another study investigating the influence of omega-3 fatty acids on fetal, neonatal, and child development Another group had moderate preeclampsia	Cod-liver oil supplement	16-20 weeks gestation through pregnancy
Helland et al., 2001	Randomized Controlled Trial	Pregnant women (n=590) Aged 19-35 years Oslo, Norway Single pregnancies, Nulli- or primipara Intention to breastfeed No supplement of n-3 LCPUFA earlier during the pregnancy No premature births, birth asphyxia, infections, and anomalies in the infants that required special attention	Cod-liver oil supplement	17-19 weeks gestation until 3 months after delivery

Amount	Results	Conclusion*
Cod-liver oil group: 10 mL/day Corn-oil group: 10 mL/day	There were no significant differences in gestational age between the four groups (cod-liver oil group, corn oil group, preeclamptic group, and the normotensive group). Birth weight was significantly higher in the corn oil group compared to the cod-liver oil group ($p<0.05$) and significantly higher in the normotensive group compared to the preeclamptic group ($p<0.0001$).	A (birth weight only)
10 mL/day cod-liver oil vs. corn oil Cod-liver oil group: 803 mg of EPA/10 mL; 1183 mg DHA/10 mL Corn-oil group: 0 mg of EPA/10 mL; 8.3 mg DHA/10 mL	"There were no significant differences in gestational length or birth weight between the two supplement groups. Birth length, head circumference, and placental weight were also similar in the 2 supplement groups."	N

continued

TABLE B-1c Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Olsen et al., 2000	Randomized Controlled Trial	Pregnant women (n=1619) 19 hospitals in Denmark, Scotland, Sweden, England, Italy, Netherlands, Norway, Belgium, and Russia Participated in one of six previous trials (four prophylactic trials and two therapeutic trials)	Fish-oil supplement	20 weeks (prophylactic) or 33 weeks (therapeutic) gestation, delivery
Olsen et al., 1992	Randomized Controlled Trial	Pregnant women (n=533) Mean age 29 years Aarhus, Denmark Main midwife clinic, covers a well-defined geographic area No placental abruption in previous pregnancy or serious bleeding in current pregnancy; no prostaglandin inhibitors regularly No multiple pregnancy, allergy to fish, and regular intake of fish oil	Fish-oil supplement	Enrolled at 30 weeks gestation; end time not specified

Amount	Results	Conclusion*
2.7 g/day fish oil vs. olive oil in the prophylactic trials 6.1 g/day fish oil vs. olive oil in the therapeutic trials	In the trial of women who experienced preterm delivery in an earlier pregnancy, those randomized to fish oil had statistically significant longer gestation duration (difference = 8.5 days) compared to those randomized to olive oil (p=0.01). In the trial of women who experienced preterm delivery in an earlier pregnancy, those randomized to fish oil had children with a significantly higher mean birth weight (difference = 208.7 g) compared to those randomized to olive oil (p=0.02). In the trial of women with threatening preeclampsia in the current pregnancy, the mean difference of duration until delivery was 8.8 days less for those randomized to fish oil compared to those randomized to olive oil (p=0.19). In the trial of women with suspected intrauterine growth retardation in the current pregnancy, the mean difference of weight for gestational age was 29 g higher in those randomized to fish oil compared to those randomized to olive oil (p=0.75).	B
2.7 g/day fish oil vs. olive oil	The average gestational length for those in the fish-oil group was 4 days longer (95% CI 1.5-6.4, $p<0.005$) than those in the olive oil group. The average gestational length for those in the fish-oil group was 2.8 days longer (95% CI 0.8-4.8, $p<0.01$)) than those in the olive-oil and control groups. Birth weight (p=0.07) and length (p=0.1) trended higher in the fish-oil group than in the olive-oil group (3 way ANOVA between fish oil, olive oil, no oil).	B

continued

TABLE B-1c Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Olsen and Secher, 1990	Randomized Controlled Trial	Pregnant women (n=5022) Aged 15-44 years London People's League of Health, 1946 Attending antenatal clinics of 10 hospitals No disease or physical abnormality	EPA/DHA supplement from halibut oil	Enrolled at <24 weeks gestation; treatment lasts for <15 weeks (n=288), 16-19 weeks (n=411), 20-23 weeks (n=414), or 24+ weeks (n=417)
People's League of Health, 1946	Randomized Controlled Trial	Pregnant women (n=5022) London Not beyond the 24th week of pregnancy No physical disease or abnormality	n-3 supplement	
People's League of Health, 1942	Randomized Controlled Trial	Pregnant women (n=5022) London	Additional diet, which includes hali-but liver oil	Enrolled if due date more than 16 weeks away; until delivery

Amount	Results	Conclusion*
0.1 g/day of EPA+DHA from halibut oil in supplement vs. no supplement Supplement includes 0.26 g ferrous iron; 0.26 g calcium; minute quantities of iodine, manganese, and copper; 0.6 g thiamin/g; 0.1 g vitamin C; 0.36 g halibut liver oil	"In primiparae, a 19.9% (p=0.012) reduction in the odds of delivering earlier than 40 weeks was seen in the treatment group, whereas in multiparae a reduction of 21.2% (p=0.028) was seen," compared to the control group. "No significant effects were seen on the odds of delivering after 40 weeks of gestation." "No significant effects were seen on average birth weight."	B (gestation only)
	"A smaller incidence of prematurely was revealed among the treated women, and this is particularly significant since about 50% of infant deaths under 1 month are due to prematurely."	B
Weekly intake score for consumption of "the more important foodstuffs" such as milk, butter, wholemeal bread, fresh vegetables, fatty fish, fruit, eggs, etc.	Among primigravida women, 20.1±1.10% of those who received additional diet experienced a preterm delivery compared to 23.9±1.10% of those who did not receive additional diet. This difference was statistically significant.	B
Additional diet: 0.26 g ferrous iron; 0.26 g calcium; minute quantities of iodine, manganese, and copper; 1 g adsorbate of vitamin B1; 100 mg vitamin C; 0.36 g halibut liver oil (vitamins A and D)	Among multiparae women, 20.1±1.33% of those who received additional diet experienced a preterm delivery compared to 24.2±1.33% of those who did not receive additional diet. This difference was statistically significant.	

continued

TABLE B-1c Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Lucas et al., 2004	Cohort	Postpartum women (n=491) and their infants Mean age of 23.7 years Inuit 14 coastal villages of Nunavik and southern Quebec Delivered at Tulattavik Health Center (Ungava Bay) or Inuulitsivik Health Center (Hudson Bay)	Cord venous sample	At delivery

Amount	Results	Conclusion*
Tertiles of EPA (% of total fatty acids): Tertile 1 = <0.21 Tertile 2 = 0.21-0.39 Tertile 3 = >0.39 Tertiles of DHA (% of total fatty acids): Tertile 1 = <2.99 Tertile 2 = 2.99-4.03 Tertile 3 = >4.03 Tertiles of %n-3 HUFA (% of total HUFA): Tertile 1 = <18.60 Tertile 2 = 18.60-22.96 Tertile 3 = >22.96	After adjusting for weight gain during pregnancy, gestational diabetes, cord blood mercury, lead, and PCB congener 153, those in the third tertile of n-3 HUFA (% of total HUFA) had significantly longer gestation (278.4 days) compared to those in the first tertile (273.0 days) ($p < 0.05$). After adjusting for pre-pregnancy weight, weight gain during pregnancy, parity, smoking status during pregnancy, gestational diabetes, age, cord blood mercury, and PCB congener 153, those in the third tertile of n-3 HUFA (% of total HUFA) had babies with a higher birth weight (3551 g) compared to those in the first tertile (3475 g), but this difference was not significant. There were no significant differences in birth weight or gestation based on the tertiles of EPA and DHA in the cord blood.	B

continued

TABLE B-1c Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Oken et al., 2004	Cohort	Pregnant women (n=2109) Aged 14-44 years 16% Black, 7% Hispanic-American, 6% Asian-American Massachusetts Project Viva	Seafood	Last menstrual period until enrollment, 3 months prior to 26-28 weeks of gestation, the month prior to delivery
Olsen and Secher, 2002	Cohort	Pregnant women (n=8729) Aarhus, Denmark Gave birth to singleton, live-born babies without detected malformations Had not consumed fish-oil supplements	Seafood	From when first knew of pregnancy until completion of questionnaires at 16 and 30 weeks gestation

Amount	Results	Conclusion*
Seafood tertiles: None or <1 serving/month, the remaining subjects were divided into tertiles with the highest intake group used as the referent	After adjusting for enrollment site, infant sex, and maternal age, height, intrapartum weight gain, pre-pregnancy BMI, race/ethnicity, smoking during pregnancy, education, and gravidity:	B
First trimester quartiles of EPA+DHA: Quartile 1 = 0.00-0.05 Quartile 2 = 0.06-0.12 Quartile 3 = 0.12-0.24 Quartile 4 = 0.24-2.53	Significant negative trends based on EPA+DHA intake were found for the first trimester [birth weight (p=0.01) and fetal growth (p=0.001)], the second trimester [fetal growth (p=0.03)], and the third trimester [birth weight (p=0.001) and fetal growth (p=0.003)];	
Second trimester quartiles of EPA+DHA: Quartile 1 = 0.00-0.05 Quartile 2 = 0.06-0.12 Quartile 3 = 0.12-0.23 Quartile 4 = 0.24-2.71	No other significant trends were observed for change in birth weight, fetal growth or length of gestation with EPA+DHA intake during the three trimesters;	
Third trimester quartiles of EPA+DHA: Quartile 1 and 2 = 0.00-0.06 Quartile 3 = 0.60-0.11 Quartile 4 = 0.11-1.72	Significant negative trends were observed for change in birth weight and fetal growth with seafood consumption, but only during the first trimester (p=0.05 and p=0.08, respectively); and No other significant trends were observed for change in birth weight, fetal growth, or length of gestation with seafood intake during the first two trimesters.	
0.0, 0.5, 2.0, 4.0, 20.0, 28.0 serving/28 days Hot fish meal: 144 g fish/serving 1627 ∝g n-3 fatty acids/serving Fish sandwich: 29 g fish/serving 431 ∝g n-3 fatty acids/serving Fish salad: 50 g fish/serving 149 ∝g n-3 fatty acids/serving	"Low birth weight, preterm birth, and intrauterine growth retardation all tended to decrease with increasing fish consumption, and mean birth weight, duration of gestation, and birth weight adjusted for gestational age tended to increase with increasing fish consumption." Low consumption of seafood was a strong risk factor for preterm delivery and low birth weight. The associations were strongest below a daily intake of 0.15 g long change n-3 fatty acids or 15 g fish.	B

continued

TABLE B-1c Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Grandjean et al., 2001	Cohort	Singleton term births (n=182) Faroe Islands Delivered at the National Hospital in Torshavn Birth at >36 weeks of gestation; no congenital neurological disease	Maternal and cord serum and seafood intake	Maternal blood taken at week 34, cord blood taken at delivery, questionnaire administered 2 weeks after parturition
Olsen et al., 1991	Cohort	Mothers of live-born singleton infants (n=99) Mean age about 27 years Faroese (n=62) and Danish women (n=37) Delivered at the Landss-jukrahusid and Aarhus Kommenehospital No preeclampsia, rhesus immu-nization, insulin-dependent diabetes mellitus, or twin pregnancies	Peripheral venous blood sample	5-48 hours after delivery

Amount	Results	Conclusion*
Information on fish species or portion sizes was not collected	Gestational length showed a significant positive association with cord serum DHA concentration ($p<0.001$) and DTA ($p=0.004$).	B
Fish dinners/week: 0, 1, 2, ε3 Whale meat dinners/month: 0, 1, ε2 Whale blubber dinners/month: 0, 1-2, >2	After adjusting for nonsmoking, average-height and nulliparous mother with term birth of male baby, birth weight showed a significant positive association with cord serum ETA ($p=0.001$), EPA ($p=0.015$), and DPA ($p=0.002$). After adjusting for gender, parity, gestational length, smoking, and maternal height, birth weight decreases by 246 g for every one unit increase in cord serum EPA concentration (%) ($p=0.037$).	
Faroese women: Mean of 0.83±0.039% EPA Mean of 2.08±0.059% DPA Mean of 5.87±0.12% DHA Mean of 12.07±0.15% AA Danish women: Mean of 0.61±0.051% EPA Mean of 2.08±0.076% DPA Mean of 4.65±0.159% DHA Mean of 12.07±0.19% AA	There were no significant differences in gestational age ($p=0.3$) and birth weight ($p=0.1$) between the two groups. After controlling for maternal pre-pregnant weight, height, age, parity, marital status, smoking, and employment during pregnancy a significant association was found between the (3/6) ratio from blood and gestational age in the Danish women ($p=0.02$) but not in the Faroese women ($p=0.6$).	N

continued

TABLE B-1c Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Harper et al., 1991	Case-control	Cases = born to Orkney Island residents, delivered in Orkney Islands (n=899) or Aberdeen (n=116) Controls = born to Aberdeen City district residents (n=2997) Singleton live births Scotland	Resident of Orkney (a proxy for eating more seafood)	

*B = Evidence of a benefit; A = Evidence of an adverse effect; N = Evidence of no association or no clear association.

Amount	Results	Conclusion*
The Orcandians eat 30% more fish than the Aberdonians, but absolute amount undetermined	Mean birth weight of the infants born to residents of Orkney Islands was 3521 g and for residents of Aberdeen was 3287 g (p=0.01). Gestational age was 0.36 weeks longer in the Orkney women than in the Aberdeen women (p=0.01). 18.3% of infants born to Orkney women and 10.0% of infants born to Aberdeen women were over the 90th percentile for birth weight (corrected for gestational age and parity) (p=0.01). 4.8% of infants born to Orkney women and 12.2% of infants born to Aberdeen women were below the 10th percentile for birth weight (corrected for gestational age and parity) (p=0.01). Being a resident of Orkney explains a significant proportion of the difference in birth weights between Orkney and Aberdeen women (R^2 = 0.489).	B

TABLE B-1d Studies on Development (Anthropometry, Visual Acuity, and Cognition): Effects on Infants of Mothers Who Increase Seafood and/or Omega-3 Fatty Acid Intake

Author	Study Type	Subjects	Exposure	Timing of Exposure
Cohen et al., 2005	Review	Aggregated 8 randomized controlled trials (one study of maternal dietary supplementation and seven studies of formula supplementation)	DHA supplement	
Jensen et al., 2005	Randomized Controlled Trial	Pregnant women (n=114 in DHA group; n=113 in control group) Aged 18-40 years Houston, TX White (75% DHA group; 79% control group) African American (19% DHA group; 13% control group) Gestational age >37 weeks Infant birth weight 2500-4200 g No chronic maternal disorders as well as major congenital anomalies and obvious gastrointestinal or metabolic disorders of the infant	DHA supplement	Day 5 after delivery until 4 months postpartum

Amount	Results	Conclusion*
	An increase in maternal intake of DHA during pregnancy of 1 g/day will increase child IQ by 0.8-1.8 points. "Prenatal maternal DHA intake increasing the child plasma (RBC) DHA phospholipid fraction by 1% has the same impact on cognitive development as formula DHA supplementation that increases the child's plasma (RBC) DHA phospholipid fraction by 1%." "Because typical DHA intake associated with fish consumption is well under 1 g/day, changes in fish consumption will result in IQ effects amounting to a fraction of a point," but they are not clinically detectable.	B
DHA capsule: Algal triacylglycerol 200 mg DHA/day Control capsule: Soy and corn oil	There were no significant differences in visual acuity (from either the Teller Acuity Card or Sweep VEP) at 4 or 8 months of age between the two groups. There were no significant differences in mean transient VEP latency at 4 and 8 months of age between the two groups; but the transient VEP amplitude was significantly lower in the infants of the DHA group compared to the infants of the control group. There were no significant differences in Gesell Gross Motor Inventory, CAT, CLAMS DQ, or Bayley MDI between the two groups at 12 or 30 months of age; but Bayley PDI at 30 months of age was 8.4 points higher (p=0.005) in infants of the DHA group compared to infants of the control group.	N

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Dunstan et al., 2004	Randomized Controlled Trial	Pregnant women (n=83) Atopic pregnancies Western Australia History of doctor diagnosed allergic rhinitis and/or asthma One or more positive skin prick test to house mites; grass pollens; molds; cat, dog, or cockroach extracts Nonsmokers No other medical problems, complicated pregnancies, seafood allergy, or >2 fish meals/week Term, healthy infants considered at high risk of allergic disease	Fish-oil supplement	20 weeks gestation until delivery
Jensen et al., 2004	Randomized Controlled Trial	Breast-feeding mothers (n=89 in treatment group; n=85 in placebo group)	DHA supplement	Delivery until 4 months postpartum

Amount	Results	Conclusion*
Fish-oil group: 3.7 g/day fish oil 56% DHA and 27.7% EPA 4 capsules/day Olive-oil group: 66.6% n-9 oleic acid and <1% n-3 PUFA 4 capsules/day	Breast milk concentrations of DHA, DPA, and EPA were significantly higher ($p<0.001$) and AA was significantly lower ($p=0.045$) in fish-oil supplemented mothers compared with controls. "There were no significant differences in the detection or level of free cytokines or IgA between the 2 groups."	N/A
200 mg/day of DHA vs. placebo	There were no significant differences between the two groups in visual function or neurodevelopment until 30 months of age. At age 30 months, the Bayley PDI of infants whose mothers were randomized to DHA was 0.55 standard deviations higher ($p<0.01$) than that of infants whose mothers were randomized to the placebo. There were no significant differences between the two groups in visual function; transient VEP; sweep VEP; stereoacuity; and gross and fine motor, executive, perceptual/visual or verbal domains at age 5. At age 5, infants whose mothers were randomized to DHA had significantly higher Sustained Attention Sub-test of the Leiter International Performance Scale than those whose mothers were randomized to the placebo ($p<0.008$).	B

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Helland et al., 2003	Randomized Controlled Trial	Pregnant women (n=48 in cod-liver oil group; n=36 in corn oil group) Aged 19-35 years Oslo, Norway Healthy women with, singleton pregnancy, nulli- or primiparous, intention to breastfeed No supplement of n-3 LCPUFA earlier during pregnancy, premature births, birth asphyxia, general infections, or anomalies in the infants that required special attention	Cod-liver oil supplement	From 18 weeks of pregnancy until 3 months after delivery

Amount	Results	Conclusion*
Cod-liver oil: 10 mL/day 1183 mg DHA, 803 mg EPA Corn oil: 10 mL/day 4747 mg LA, 92 mg ALA	K-ABC scores were significantly higher for the sub-set MPCOMP among children from the cod-liver oil group compared to the corn oil group (p=0.049). The scores for the other subtests (SEQPROC, SIMPROC, NONVERB) were also higher in the cod-liver oil group compared to the corn oil group, but they were not significant.	B

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Auestad et al., 2001	Randomized Controlled Trial	Infants (n=294 formula fed; n=165 breastfed) Kansas City, MO; Little Rock, AR; Pittsburgh, PA; Tucson, AZ Good health, term status, either δ9 days of age (formula group) or δ11 days of age and currently breastfeeding (breastfeeding group), birth weight ε2500 g, 5-minute APGAR score ε7, ability to tolerate milk-based formula or breast milk, guardian or parent agreement to feed the assigned study formula ad libitum according to the study design No evidence of significant cardiac, respiratory, ophthalmologic, gastrointestinal, hematologic, or metabolic disease; milk-protein allergy; or a maternal medical history known to have proven adverse effects on the fetus, tuberculosis, HIV, perinatal infections, or substance abuse 61-74% European American 60-80% mothers married Mean mother's age about 29 years Mean mother's education about 14 years	Fish oil/fungal oil and egg-derived triglyceride supplemented formulas	9-11 days after birth until 12 months of age

Amount	Results	Conclusion*
Fish oil and fungal oil supplemented preterm formula: 0.46 g AA/100 g total fatty acids δ0.04 g EPA/100 g total fatty acids 0.13 g DHA/100 g total fatty acids	The vocabulary expression score at 14 months was significantly higher in the fish/fungal group than in the egg-TG group ($p<0.05$). Smiling and laughter was significantly higher in the control group than in the egg-TG group ($p=0.05$). No other development, cognition, vocabulary, or temperament outcomes presented were significantly difference between the formula groups.	N
Egg-derived triglyceride supplemented preterm formula: 0.45 g AA/100 g total fatty acids No detected EPA 0.14 g DHA/100 g total fatty acids Control formula: No detected AA, EPA, DHA	No significant differences were found between groups for weight, length, and head circumference or visual acuity.	

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Helland et al., 2001	Randomized Controlled Trial	Pregnant women (n=590) Aged 19-35 years Oslo, Norway Single pregnancies, nulli- or primipara Intention to breastfeed No supplement of n-3 LCPUFA earlier during the pregnancy No premature births, birth asphyxia, infections, and anomalies in the infants that required special attention	Cod-liver oil supplement	17-19 weeks gestation until 3 months after delivery
McCann and Ames, 2005	Review	Summary of observational, RCTs, other experimental and animal studies	LCPUFA supplement	

Amount	Results	Conclusion*
10 mL/day cod-liver oil vs. corn oil Cod-liver oil: 803 mg of EPA/ 10 mL; 1183 mg DHA/10 mL Corn oil: 0 mg of EPA/ 10 mL; 8.3 mg DHA/10 mL	"There were no significant differences in gestational length or birth weight between the 2 supplement groups. Birth length, head circumference, and placental weight were also similar in the 2 supplement groups."	N
	"Evidence from chronic dietary restriction rodent studies . . . shows that the addition of DHA to diets of animals whose brain concentration of DHA have been severely reduced restored control performance levels." "Formula comparison and maternal supplementation studies in humans and ALA dietary restriction studies in nonhuman primates both link the availability of n-3 LCPUFAs to the development of visual attention" and higher DHA status to enhanced neuromotor development. RCTs in humans have often shown no effect of "LCPUFA supplementation on cognitive or behavioral performance and some reviewers have considered that, overall, the evidence was insufficient to conclude that LCPUFA supplementation benefited development."	B

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Koletzko et al., 2001	Review	Studies published in full or in abstract form	LCPUFA supplement	Prenatal and postnatal periods
Makrides and Gibson, 2000	Review	Summary of the evidence	LCPUFA supplement	During pregnancy and lactation

Amount	Results	Conclusion*
	"Breastfeeding, which supplies preformed LCPUFA, is the preferred method of feeding for healthy infants and is strongly supported."	B
	"Infant formulas should contain at least 0.2% of total fatty acids as DHA and 0.35% as AA; formulas for preterm infants should include at least 0.35% DHA and 0.4% AA."	
	There is an absence of published studies showing direct functional benefits of supplementation of LCPUFA and studies to determine if the variability in LCPUFA status among pregnant women is related to functions in either the mother or infant.	
	"It seems prudent for pregnant and lactating women to include some food sources of DHA in their diet."	
	"There appears to be no detectable reduction in plasma n-3 LCPUFA concentrations during pregnancy, whereas there is a clear decline during the early postpartum period."	B
	"Results of randomized clinical studies suggest that n-3 LCPUFA supplementation during pregnancy does not affect the incidences of pregnancy-induced hypertension and preeclampsia without edema."	
	"n-3 LCPUFA supplementation may cause modest increases in the duration of gestation, birth weight, or both."	
	"To date there is little evidence of harm as a result of n-3 LCPUFA supplementation during either pregnancy or lactation."	

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Leary et al., 2005	Cohort	Mother-child pairs (n=6944) Bristol, England Avon Longitudinal Study of Parents and Children (ALSPAC)	Diet	During pregnancy, unspecified

Amount	Results	Conclusion*
Carbohydrate (g) 182-218, 218-258, >258 Protein (g) 55-66, 66-79, >79	After adjusting for sex, child's age for blood pressure, and maternal pregnancy energy intake, a significant inverse association was found between omega-3 fatty acids and offspring blood pressure at age 7.5 years (p=0.04).	N
Total fat (g) 55-68, 68-84, >84 Saturated fat (g) 21-27, 27-35, >35 Polyunsaturated fat (g) 9-12, 12-16, >16 Monounsaturated fat (g) 19-24, 24-30, >30	After adjusting for sex, child's age for blood pressure, and maternal pregnancy energy intake, there were no significant differences in offspring blood pressure at age 7.5 years based on maternal intake of carbohydrate, protein, total fat, saturated fat, polyunsaturated fat, monounsaturated fat, calcium, potassium, magnesium, protein/carbohydrate or animal protein. After adjusting for measurement factors, current anthro - pometry, maternal and social factors, birth weight, and gestation, there was a significant positive association found between maternal intake of carbohydrates and offspring blood pressure at 7.5 years (p=0.04).	
Calcium (mg) 759-938, 939-1127, >1127 Potassium (mg) 2177-2582, 2583-3021, >3021 Magnesium (mg) 207-254, 255-308, >308 Protein/carbohy- drate 0.26-0.30, 0.31-0.35, >0.35 Animal protein (g) 35-44, 44-53, >53 Omega-3 fatty acids (g) 0.03-0.09, 0.10-0.27, >0.27	After adjusting for measurement factors, current anthro - pometry, maternal and social factors, birth weight, and gestation, there were no significant differences between the tertiles of maternal intake of protein, total fat, saturated fat, polyunsaturated fat, monounsaturated fat, calcium, potassium, magnesium, protein/carbohydrate, animal protein, or omega-3 fatty acid and offsprings' systolic blood pressure at age 7.5 years.	

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Oken et al., 2005	Cohort	Mother-infant pairs (n=135) Aged <30 years (n=16) Aged 30-34 years (n=53) Aged ε35 years (n=31) 82% White; 18% non-White 80% college or graduate degree Massachusetts Singleton pregnancy, were able to complete forms in English, did not plan to move out of the study area before delivery Project Viva	Seafood	Second trimester of pregnancy
Colombo et al., 2004	Cohort	Infants (n=70) Mean gestation 39.29 weeks Mean birth weight 3248.57 g Mean APGAR score (1 min) 7.94 Mean APGAR score (5 min) 8.80 Mean education (11.77 years for mother and 11.88 for father) 77% African American 21% Caucasian 1% Hispanic Kansas	DHA-enriched egg	24-28 weeks gestation until delivery

Amount	Results	Conclusion*
Number of servings/week: Canned tuna fish (3-4 oz/serving) Shrimp/lobster/ scallop/clam (1 serving) Dark meat fish (3-5 oz/serving) Other fish (3-5 oz/serving)	After controlling for maternal hair mercury level, age, race/ethnicity, education, marital status, infant sex, gestational age at birth, birth weight for gestational age, breast-feeding duration and age at cognitive testing: Each 1 serving/week increase of fish intake increases the VRM score by 4 points (%novelty preference; 95% CI 1.3-6.7).	B
6 responses from never or less than 1/month to 1 or more servings/day	After controlling for maternal seafood intake, age, race/ethnicity, education, marital status, infant sex, gestational age at birth, birth weight for gestational age, breast-feeding duration, and age at cognitive testing: Each 1 ppm increase in maternal hair mercury levels decreases the VRM score by 7.5 points (%novelty pref - erence; 95% CI ↕13.7 to ↕1.2).	
This study is a follow-up to an RCT High-DHA eggs: 135 mg DHA/ egg Ordinary eggs: 35 mg DHA/egg	"Infant red blood cell DHA level was unrelated to sub - sequent attentional measures, but maternal red blood cell DHA was consistently predictive of later attentional outcomes." "Infants whose mothers had higher levels of DHA at birth showed accelerated developmental courses in at - tention across the 1st year." Percent of time spent looking in orienting increased over time in both the high- and low-DHA groups, but it was larger in the high-DHA group compared to the low-DHA group at 4, 6, and 8 months. Percent of time spent looking in sustained attention declined over time in both groups, but it was smaller in the high-DHA group compared to the low-DHA group at 4, 6, and 8 months. Percent of time spent looking in attention termination was larger at 4 months in the low-DHA group com - pared to the high-DHA group, and then declined and leveled off at 6 months in both groups.	B

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Daniels et al., 2004	Cohort	Infants (n=1054) Mothers' mean age = 29 years Majority of mothers with at least an *O* (moderate) level education Bristol, UK Singleton, term births Avon Longitudinal Study of Parents and Children (ALSPAC)	Seafood	Maternal fish intake: 32 weeks of gestation Breastfeeding practices: 15 months after birth Infant fish intake: 6 and 12 months after birth Total mercury concentration: Cord blood at birth
Sakamoto et al., 2004	Cohort	Pregnant women (n=63) Aged 21-41 years Japan Planning to deliver at Munakata Suikokai General Hospital, Fukuoka Healthy	Maternal blood and umbilical cord blood lipids	Umbilical cord blood at birth and maternal blood 1 day after parturition before breakfast

Amount	Results	Conclusion*
Maternal fish intake categories (during pregnancy): 1 = Rarely/never 2 = 1 meal/2 weeks 3 = 1-3 meals/week 4 = 4+ meals/week	Children whose mothers ate 1-3 fish meals/week and 4+ fish meals/week had significantly lower odds of low MCDI scores for social activity (OR=0.6, 95% CI 0.5-0.8 and OR=0.7, 95% CI 0.5-0.9, respectively) than the children whose mothers rarely or never ate fish during pregnancy.	B
Child fish intake categories (6 months of age): 1 = Rarely/never 2 = 1+ meal/week	Children whose mothers ate 1-3 fish meals/week and 4+ fish meals/week had significantly lower odds of low DDST scores for language (OR=0.7, 95% CI 0.5-0.9 and OR=0.7, 95% CI 0.5-0.9, respectively) than the children whose mothers rarely or never ate fish during pregnancy.	
Child fish intake categories (12 months of age): 1 = Rarely/never 2 = 1+ meal/week	Children who ate 1+ fish meals/week had significantly lower odds of low MCDI scores for vocabulary comprehension (OR=0.7, 95% CI 0.5-0.8) and social activity (OR=0.7, 95% CI 0.6-0.9) and total DDST scores (OR=0.8, 95% CI 0.6-0.9). All other odds ratios presented were nonsignificant.	
Unspecified	In all cases, fetal RBC-Hg levels (13.4 ng/g) were statistically higher than maternal RBC-Hg levels (8.41 ng/g) ($p<0.01$). "A strong correlation was observed in RBC-Hg between mothers and fetuses ($r=0.92$, $p<0.001$)." "Maternal RBC-Hg concentrations showed significant correlation coefficients with maternal plasma EPA ($r=0.36$, $p<0.001$) and DHA ($r=0.33$, $p<0.005$) concentrations." "Fetal RBC-Hg concentrations showed a significant positive correlation with fetal plasma EPA ($r=0.32$, $p<0.05$) and DHA ($r=0.35$, $p<0.01$)."	N/A

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Willatts et al., 2003	Cohort	Mother and infant pairs (n=96) Term pregnancy and infant birth weight >2499 g Dundee	DHA and AA content in maternal red blood cells	34-36 weeks gestation
Cheruku et al., 2002	Cohort	Pregnant women (n=17) Men aged 29 years in the high-DHA group Men aged 24 years in the low-DHA group White (n=14) Hispanic (n=3) Windham, CT ε4 hours of crib time in the first and second days postpartum No history of chronic hypertension, hyperlipidemia, renal or liver disease, heart disease, thyroid disorders, multiple gestations, or pregnancy-induced complications No drugs that affect the respiration of newborns, such as magnesium sulfate and butorphanol	Maternal plasma DHA	Day 1 and day 2 postpartum

Amount	Results	Conclusion*
Absolute DHA and AA levels in blood unspecified	After adjusting for maternal education, social class, birth weight, gestation, type of feeding at birth, and infant age at time of assessment: "There was a significant negative relation between maternal DHA and peak look duration ($p < 0.05$), and a significant positive relation between maternal DHA and visual acuity ($p < 0.01$)" at 4 months of age. The relation between AA and peak look duration and visual acuity at 4 months of age were not significant. "These results suggest that higher maternal DHA status is related to more efficient information processing and improved visual acuity development in 4-month-old infants."	B
High-DHA group (maternal plasma): >3.0% by weight of total fatty acids Low-DHA group (maternal plasma): δ3.0% by weight of total fatty acids	On day 2 postpartum, the low-DHA group had significantly higher sleep-wake transition (% of time in crib) and less wakefulness (% time in crib) than the high-DHA group ($p < 0.05$). There was a significant group effect for active sleep time ($p = 0.004$) and active:quick sleep time ($p = 0.001$), these times being shorter in the high-DHA group than in the low-DHA group. "Differences in the prenatal supply of LCPUFAs, especially DHA, may modify brain phospholipids and affect neural function."	B

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Haggerty et al., 2002	Cohort	Mothers, smokers (n=11) Mothers, nonsmokers (n=13) Aberdeen, Scotland Uncomplicated, full-term pregnancies Perfusion on term placentas delivered vaginally or by elective Caesarean section from otherwise uncomplicated pregnancies	Placental tissue lipids	Within 20 minutes of delivery
Innis et al., 2001	Cohort	Infants (n=83) Term Birth weight 2500-4500 g Mean mother's age of 32 years British Colombia Intend to breast-feed for 3 months, no solid foods for at least the first 4 months after birth No mothers with substance abuse, communicable diseases, metabolic or physiologic problems, infections likely to influence fetal growth, or multiple births No infants with evidence of metabolic or physical abnormalities	Fatty acids in blood from infants and milk from mothers	2 months of age

Amount	Results	Conclusion*
Unspecified	The rates of transfer of LA and AA per perfused area were not different between the groups; "neither was the rate of placental transfer of ALA and DHA affected by smoking during pregnancy." "In the non-smoking control group the placenta selectively transferred polyunsaturated fatty acids to the fetus in the order DHA > AA > ALA > LA. The order of selectivity was unaltered in placentas from smokers, but the addition of ethanol to the perfusion medium altered the order of selectivity to AA > ALA > LA > DHA." "The presence of ethanol in the perfusate at a concentration of 2 mg/ml significantly reduced ($p < 0.01$) the absolute rate of transfer of ALA and DHA."	N/A
Infant DHA: (g/100 g fatty acids) Plasma phospholipids = 2.2-8.0 RBC PE = 6.3-13.0 PC = 1.4-4.6 Infant AA: (g/100 g fatty acids) Plasma phospholipids = 8.1-15.8 RBC PE = 20.2-27.8 PC = 5.6-9.7 Mother's milk: (g/100 g milk fatty acids) DHA = 0.10-2.50 AA = 0.20-0.81 LA = 6.30-21.50 LNA = 0.50-4.10	"The ability to correctly discriminate a retroflex compared with dental phonetic contrast at 9 months of age was positively correlated with the plasma phospholipid DHA ($p<0.02$) and the RBC PE at 2 months of age ($p=0.02$)." "There were no significant correlations between the infants' AA status and the ability to discriminate the native or nonnative language contrasts." "There were no significant correlations between the infant DHA or AA status at 2 months of age and test scores for novelty preference, or the job search task, with adjustments for covariates included in the model."	B

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Otto et al., 2001	Cohort	Pregnant women (n=57) Mean age around 30 years Southern Limburg, Netherlands No metabolic, cardiovascular, neurologic, or renal disorders No medications, except multivitamins and iron supplements Singleton pregnancy Term delivery No blood transfusions in the perinatal period	Plasma phospholipids	36-37 weeks gestation; 2-5 days after delivery; 1, 2, 4, 8, 16, 32, 64 weeks postpartum
Williams et al., 2001	Cohort	Boys and girls (n=435) Mean age of 3.5 years Born in last 6 months of the Avon Longitudinal Study of Parents and Children (ALSPAC) enrollment period Healthy term infants	Seafood	During pregnancy for the mothers and at 4 weeks, 4 months, and 6 months for the infants

Amount	Results	Conclusion*
Absolute amount not specified	"After delivery, total fatty acids in plasma phospholipids decreased significantly over time in the lactating and nonlactating women ($p<0.0001$)." "The amounts of ALA, DHA, and total n-3 fatty acids showed significant downward trends postpartum in both groups, whereas the amounts of EPA and DPA increased significantly after delivery."	N/A
Oily fish consumption categories: 1 = Never or rarely 2 = Once every 2 weeks 3 = More than once every 2 weeks White fish = cod, haddock, plaice, and fish fingers Oily fish = pilchards, sardines, mackerel, tuna, herring, kippers, trout, and salmon	After adjusting for breastfeeding, sex, maternal education, maternal age, housing tenure, financial difficulties, maternal smoking, number of older siblings in household, child care, maternal job status, mother is a vegetarian, mother's fish eating habits: "Mothers who ate oily fish at least once every 2 weeks during pregnancy were more likely to have children who achieved foveal steroacuity than were the mothers who never ate oily fish (OR=1.57, 95% CI 1.00-2.45)," but this was not significant.	B

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Haggerty et al., 1999	Cohort	Pregnant women (n=10) Mean age of 31.3 years In last trimester of pregnancy 31-38 weeks gestational age Aberdeen, Scotland Healthy	Fatty acid composition of maternal perfusate	31-38 weeks gestation
Haggerty et al., 1997	Cohort	Term placentae (n=9) Mean weight of 566 g Delivered vaginally or by elective caesarean section Uncomplicated pregnancies Nonsmokers	Placental tissue lipids	Within 20 minutes of delivery
Al et al., 1995	Cohort	Pregnant women (n=110) Aged 19-43 years Maastricht, Netherlands Caucasian Singleton pregnancy DBP <90 mmHg No metabolic, cardiovascular, neurological or renal disorder	Maternal venous and umbilical vein fatty acid profiles	10, 14, 18, 22, 26, 30, 32, 34, 36, 38, 40 weeks gestation; after delivery; 6 months after delivery

Amount	Results	Conclusion*
Unspecified	"When perfused with fatty acids in the ratios found in maternal circulating triglyceride, the human placenta selectively transfers PUFA to the fetus in the order: DHA > ALA > LA > AA." "The ultimate source of fatty acids for the placenta is important for estimates of the likely supply of individual PUFA/LCPUFA to the fetus in utero." "The biggest determinant of transfer of individual fatty acids from the mother to fetus is the supply of fatty acids available in the maternal circulation."	N/A
Unspecified	"The order of selectivity for placental transfer to the fetal circulation was DHA > ALA > LA > oleic acid, whilst the proportion of AA transferred was actually lower than that for oleic acid." "There was no evidence of chain elongation of LA or ALA to any LCPUFA of the n-6 or n-3 series in the perfused placenta."	N/A
Absolute amount not specified	"The average amount of total fatty acid in maternal venous plasma phospholipids increased significantly ($p<0.0001$) during pregnancy, but the rise in total fatty acids became less pronounced towards the end of gestation ($p<0.0001$)." Total fatty acids increased from 1238.11 mg/L at week 10 to 1867.84 mg/L at week 40 of gestation, and all of the fatty acid families showed a similar course. "The mean amount of total fatty acids in umbilical plasma phospholipids was substantially lower ($p <0.0001$) than all maternal values" for all fatty acid families. "In contrast to the absolute amounts of AA and DHA, the mean relative amounts of AA and DHA in umbilical plasma phospholipids were significantly ($p <0.0001$) higher than all maternal values."	N/A

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Clandinin et al., 1980b	Cohort	Male infants (n=14) Female infants (n=7) Died within 3 days of birth Toronto, Canada Infants died from intrapartum asphyxia, congenital heart disease, sudden infant death syndrome, diaphragmatic hernia, and accidental causes Infants were of normal body weight and weight for length, with the exception of two infant males; infants had normal head circumference, with the exception of one infant male No infections or gastrointestinal disorders, apparently normally nourished, and growing reasonably well until the time of death	Tissue fatty acid content from frontal and occipital brain lobes and cerebellum	16 hours postmortem
Bjerve et al., 1993	Case-control	Cases = adults (n=156) Controls = normal human serum stored at –80 degrees C Aged >40 years Nord-Trondelag, Norway Previously undiagnosed diabetic patients Preterm infants (n=21) Very low birth weight, with birth weight <1500 g seen consecutively at the Department of Pediatrics	Seafood and dietary DHA and AA intake	10 weeks for adults and 1 year for the preterms

Amount	Results	Conclusion*
	"Postnatal brain growth, expressed as wet weight of brain tissue, increased during the postpartum period, but was not as rapid as intrauterine brain growth." "In contrast to the fatty acid components, postpartum levels of LA increased 4-fold relative to prenatal levels; postpartum brain levels of AA do not differ from those observed in brain during the third trimester." "Chain elongation-desaturation of AA and LA to longer-chain homologues does not occur at maximal rates for several weeks postnatally or, alternatively, that these long-chain homologues if synthesized in extracere - bral tissues may not be directed into synthesis of brain tissue during this early period of infant development."	N/A
Number of fish meals per week: <2, 2, 3, and ≥4 Mean AA intake of these groups: (g/day) 1.22, 1.19, 1.31, 1.59	"After controlling for age, gender, BMI, alcohol intake, and smoking, there was a statistically significant positive correlation based on individual observations between increasing number of fish meals and the concentra - tion of plasma phospholipid EPA ($p < 0.001$) and DHA ($p < 0.001$)." After controlling for APGAR score and weight at 1 year, 82% of the variance in MDI was explained by a model including the inverse of both DHA and EPA ($p = 0.0001$). After controlling for weight at 1 year, 64% of the vari - ance in PDI was explained by a model including the inverse of DHA ($p = 0.0001$).	B

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Uauy et al., 1990	Case-control	Case = infants fed formula by day 10 (n=32) Control = infants fed their own mother's milk from birth (n=10) Birth weight appropriate for gestational age, able to receive enteral feedings, free of major neonatal morbidity by day 10	Human milk and milk formula	Day 10 until 36 weeks old
Makrides et al., 1994	Cross-sectional	Male infants (n=16) Female infants (n=19) Died between weeks 2 and 48 South Australia All but two born at term	Human milk and milk formula	Within 48 weeks of birth

Amount	Results	Conclusion*
Human milk: 12.7 g/100 g AA, 1.5 g/100 g n-6 > C18, 0.8 g/100 g ALA, 0.5 g/100 g n-3>C18	"Group C was comparable to the human milk-fed group, but Group A had lower DHA and n-3 LCPUFA in plasma and RBC membranes." "Cone function was not affected by dietary essential fatty acids."	N/A
Formula A: 24.2 g/100 g AA, 0.0 g/100 g n-6 > C18, 0.5 g/100 g ALA, 0.0 g/100 g n-3>C18 Formula B: 20.8 g/100 g AA, 0.0 g/100 g n-6 > C18, 2.7 g/100 g ALA, 0.0 g/100 g n-3>C18 Formula C: 20.4 g/100 g AA, 0.1 g/100 g n-6 > C18, 1.4 g/100 g ALA, 1.0 g/100 g n-3>C18	"Rod electroretinogram thresholds were significantly higher for Group A relative to the human milk-fed infants and Group C and significantly correlated with RBC n-3 LCPUFA ($p<0.0001$)." "Rod electroretinogram amplitude was significantly lower for Group A relative to the human milk-fed infants and Group C and related to plasma DHA and total n-3 LCPUFA ($p<0.0001$)."	
Breast-feeding index = length of breastfeeding as a % of age at death: Breast-fed: ε85% Formula fed: <30% LA in formula ranged from 12.0% to 15.0% and ALA in formula ranged from 1.0% to 1.6%	Erythrocyte fatty acid composition of tissues were significantly lower in total saturated fatty acids ($p<0.05$), AA ($p<0.05$), and DHA ($p<0.05$) and significantly higher in DGLA ($p<0.05$), EPA ($p<0.05$), and DPA ($p<0.05$) for infants fed formula compared to those fed from the breast. Cortex fatty acid composition of tissues were significantly higher in 22:4n-6 ($p<0.05$), 22:5n-6 ($p<0.05$), and total n-6 ($p<0.005$) and lower in DHA ($p<0.005$) and total n-3 ($p<0.005$) for infants fed formula compared to those fed from the breast. There were no significant differences in retina fatty acid composition of tissues between the formula-fed and breast-fed infants.	B

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Farquharson et al., 1992	Cross-sectional	Term infants (n=20) Preterm infants (n=2) Greater Glasgow Health Board area Died within 43 weeks of birth Previously well infants who died suddenly in the home, "cot deaths"	Human milk and milk formula	Within 43 weeks of birth
Martinez, 1992	Cross-sectional	Infants born at different gestational ages and died soon after birth of acute causes that were not related to the central nervous system Not fed but mothers well-nourished Infants nourished in utero and after birth	PUFA supplementation and PUFA-enriched formula	After infant died (they died shortly after birth)

Amount	Results	Conclusion*
Breast milk or the formula milks SMA Gold Cap and/or White Cap, Cow and Gate Premium, or Osterfeed	"Breast fed infants had greater concentrations of DHA in their cerebral cortex phospholipids than either the mixed fed group or the older SMA and CGOST groups." "No significant differences in phospholipid fatty acid content of cerebral cortex were found between the age-comparable SMA and CGOST groups."	N/A
Prenatal fatty acid amounts not specified	"Long-chain fatty acids accumulate in the human brain during the brain's growth spurt unless a serious imbal - ance in the supply of LA and ALA occurs." "The active formation of synaptic structures and den - dritic arborizations increases significantly between 31 weeks of gestation and term." "It seems highly desirable to enrich parenteral lipids and milk formulas with DHA to provide between 0.5% and 1% of total fatty acids similar to those in human milk." "A total n-6/n-3 fatty acid ratio between 5 and 7 seems appropriate according to our analysis of human milk from others consuming complete, balanced Mediterra - nean diets rich in fish."	B

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Kodas et al., 2004	Animal	2 generations of female Wistar rats	ALA-deficient diet	Control group: Control diet at birth to 60 days after birth Deficient group: Deficient diet at birth to 60 days after birth Diet reversed group 1: Control diet at day of birth until 60 days after birth Diet reversed group 2: Deficient diet until day 7 of life and then control diet from day 7 to day 60 of life Diet reversed group 3: Deficient diet until day 14 of life and then control diet from day 14 to day 60 of life Diet reversed group 4: Deficient diet until day 21 of life and then control diet from day 21 to day 60 of life

Amount	Results	Conclusion*
ALA-deficient diet: 6% fat African peanut oil <6 mg ALA/100 g diet 1200 mg LA/100 g diet Control diet: 60% peanut oil, 40% rapeseed oil 200 mg ALA/100 g diet 1200 mg LA/100 g diet	The fatty acid composition of phosphatidylcholine in the hippocampus of 2-month-old rats was as follows: AA was not significantly different among the different diet groups; DHA was significantly higher in the control group and all diet reversed groups compared to the defi - cient group ($p<0.05$); n-6:n-3 was significantly lower in the control group and all diet reversed groups compared to the deficient group ($p<0.05$); these differences were not significant between the control group and the diet reversed groups. The fatty acid composition of phosphatidylethanolamine in the hippocampus of 2-month-old rats was as follows: AA was significantly lower in the control group and all diet reversed groups compared to the deficient group ($p<0.05$); DHA was significantly higher in the control group and all diet reversed groups compared to the defi - cient group ($p<0.05$); n-6:n-3 was significantly lower in the control group and all diet reversed groups compared to the deficient group ($p<0.05$); these differences were not significant between the control group and the diet reversed groups. The fatty acid composition of phosphatidylserine in the hippocampus of 2-month-old rats was as follows: AA was not significantly different among the different diet groups; DHA was significantly higher in the control group and all diet reversed groups compared to the defi - cient group ($p<0.05$); n-6:n-3 was significantly lower in the control group and all diet reversed groups compared to the deficient group ($p<0.05$); these differences were not significant between the control group and the diet reversed groups; and Basal 5-HT levels were significantly higher in the defi - cient group compared with the control group ($p <0.05$); there were no significant differences in basal 5-HT levels between the diet reversed groups 1, 2, and 3 and the control group; there were no significant differences in basal 5-HT levels between the diet reversed group 4 and the control group, deficient group, and all other diet reversed groups.	B

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Korotokova et al., 2004	Animal	Pregnant Sprauge-Dawley rats	n-6:n-3 diet, n-3 diet, and n-6 diet	10 days before delivery 10-16 days of lactation, dam fed water with ovalbumin or just water

Amount	Results	Conclusion*
n-6:n-3 diet (in mol%): 7.0% soybean oil 56.0% LA, 6.2% ALA, 9.0% n-6:n-3 n-3 diet (in mol%): 7.0% linseed oil 14.0% LA, 33.0% ALA, 0.4% n-6:n-3 n-6 diet (in mol%): 7.0% sunflower oil 65.0% LA, 0.3% ALA, 216.0% n-6:n-3	In the pups not exposed to ovalbumin: Delayed-type hypersensitivity responses against ovalbumin, as well as against human serum ovalbumin were not significantly different between the dietary groups; IgG anti-avalbumin and IgG anti-human serum ovalbumin antibodies were not significant different between the three diet groups; IgM anti-ovalbumin antibodies in the n-3 diet group are significantly higher than those in the n-6:n-3 diet group ($p<0.05$); and IgM anti-human serum ovalbumin antibodies in the n-3 diet group are significantly higher that those in the n-6:n-3 diet group ($p<0.05$). In the pups exposed to ovalbumin: Delayed-hypersensitivity responses against ovalbumin were significantly higher in the n-6:n-3 diet group compared to the n-3 diet group and the n-6 diet group, while delayed-hypersensitivity responses to human serum ovalbumin were significantly higher in the n-6:n-3 diet group compared to the n-3 diet group ($p<0.05$); IgG anti-human serum ovalbumin antibodies were significantly higher in the n-6:n-3 diet group than those in the n-3 diet group ($p<0.05$); and IgM anti-human serum ovalbumin antibodies in the n-3 diet group are significantly lower than those in the n-6:n-3 diet group and the n-6 diet group ($p<0.05$). Those in the n-3 diet group exposed to ovalbumin have significantly lower IgG ovalbumin, IgG anti-human serum ovalbumin, IgM anti-ovalbumin, and IgM anti-human serum ovalbumin antibodies than those not exposed to ovalbumin ($p<0.05$). Those in the n-6 diet group exposed to ovalbumin have significantly lower IgG ovalbumin and IgM anti-ovalbumin antibodies than those not exposed to ovalbumin ($p<0.05$).	B

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Levant et al., 2004	Animal	Adult female Long-Evans rats	LCPUFA-deficient diet	Control diet: Day 1 of pregnancy until end of study Deficient diet: Day 1 of pregnancy until postnatal day 21. Postnatal day 21, half on deficient diet were changed to remediation diet and half stayed on deficient diet

Amount	Results	Conclusion*
Control diet: 0.35 kg/5 kg diet from soybean oil; no detected AA, EPA, DPA, or DHA Deficient diet: 0.35 kg/5 kg diet from sunflower oil; no detected AA, EPA, DPA, or DHA Remediation diet: 0.3275 kg/5 kg diet from sunflower oil and 0.0225 kg/5 kg diet from fish oil 0.1 g/100 g fatty acids AA, 1.6 g/100 g fatty acids EPA, 0.4 g/100 g fatty acids DPA, 3.5 g/100 g fatty acids DHA	"Rats raised on the deficient diet exhibited a decrease in brain DHA content to 80% of control animals at maturity ($p<0.05$)" and an "increase in DPA content to 575% of control animals at maturity ($p<0.001$)." The remediation diet restored brain DHA and DPA content to levels similar to those on the control diet. Catalepsy score was significantly lower in the deficient diet group compared to the control group ($p<0.05$) and the remediation diet group ($p<0.05$). In a test of locomotor activity in a novel environment, the deficient diet group exhibited 187% of the activity of the control diet group during the 2-hour observation ($p<0.05$); results were similar between the deficient diet group and the remediation diet group. In the test of amphetamine-stimulated locomotor activity, the deficient diet group exhibited 144% of the activity of the control group ($p<0.05$).	A

continued

TABLE B-1d Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Neuringer et al., 1986	Animal	Adult female rhesus monkeys	n-3-deficient diet	2 months before conception and throughout pregnancy

*B = Evidence of a benefit; N = Evidence of no association or no clear association; N/A = A conclusion is not available; these data are presented for background information only; A = Evidence of an adverse effect.

Amount	Results	Conclusion*
Semipurified diet: Deficient in n-3 fatty acids Safflower oil was sole fat source High n-6:n-3 ratio Controls: Soybean oil was sole fat source High in LA	At all ages, animals of the "deficient group had considerably lower levels of n-3 fatty acids in tissue phospholipids than their controls." Based on the occipital cortex, perinatal 22:5n-6 ($p<0.01$) and total n-6 ($p<0.05$) were significantly higher and perinatal DHA ($p<0.01$) and total n-3 ($p<0.01$) were significantly lower in the deficient group compared to the control group. Based on the occipital cortex, 22:4n-6 ($p<0.01$), 22:5n-6 ($p<0.01$), and total n-6 ($p<0.01$) at 22 months were significantly higher and DHA ($p<0.01$) and total n-3 ($p<0.01$) at 22 months were significantly lower in the deficient group compared to the control group. Based on the frontal cortex, perinatal 22:5n-6 ($p<0.01$) was significantly higher and perinatal DHA ($p<0.01$) and total n-3 ($p<0.01$) were significantly lower in the deficient group compared to the control group. Based on the frontal cortex, 22:5n-6 ($p<0.01$) and total n-6 ($p<0.01$) at 22 months were significant higher and DHA ($p<0.01$) and total n-3 ($p<0.01$) at 22 months were significantly lower in the deficient group compared to the control group.	N/A

TABLE B-1e Studies on Allergies: Effects on Infants and Children of Mothers Who Increase Seafood and/or Omega-3 Fatty Acid Intake

Author	Study Type	Subjects	Exposure	Timing of Exposure
Denburg et al., 2005	Randomized Controlled Trial	Pregnant women (n=83) Booked for delivery at St. John of God Hospital Subiaco, Western Australia With confirmed allergy No smoking, other medical problems, complicated pregnancies, seafood allergy; normal dietary intake did not exceed two meals of fish per week	Fish-oil supplement	20 weeks of pregnancy until delivery

Amount	Results	Conclusion*
Fish oil group: 3.7 g of n-3 PUFA 56.0% as DHA and 27.7% as EPA Placebo group: 2.6 g olive oil 26 g/day oleic acid	Infants of those in the fish oil group had a significantly higher %CD34 expression than infants of those in the placebo group ($p<0.002$). There was no significant difference between the two groups with respect to expression of all cytokine and chemokine receptors. There was a significant association found between CD34+ in cord blood and AEDS (OR=3.93; 95% CI 1.05-14.64, p=0.042) at one year of age; however, there were no significant associations found for food allergy, moderate severe AEDS, asthma, chronic cough, or recurrent wheeze. There were significant associations found between cord blood progenitor responsiveness to IL-5 and AEDS (OR=1.09, 95% CI 1.00-1.18, p=0.039) and recurrent wheeze (OR=1.11, 95% CI 1.02-1.21, p=0.022) at one year of age; however, there were no significant associations found for food allergy, moderate severe AEDS, asthma, or chronic cough.	B

continued

TABLE B-1e Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Dunstan et al., 2003a	Randomized Controlled Trial	Pregnant women (n=83) Atopic women Booked for delivery at St. John of God Hospital Subiaco, Western Australia Physician-diagnosed allergic rhinitis and/or asthma Allergic to house dust mites, grass pollens, molds, cat, dog, feathers, and cockroach and/or asthma No medical problems, no smoking, no complicated pregnancies, no seafood allergy; normal diet did not exceed two meals of fish per week	Fish-oil supplement	20 weeks of pregnancy until delivery
Dunstan et al., 2003b	Randomized Controlled Trial	Pregnant women (n=83) Atopic women Booked for delivery at St. John of God Hospital Subiaco, Western Australia Physician-diagnosed allergic rhinitis and/or asthma Allergic to house dust mites, grasses, molds, cat, dog, feathers, and cockroach and/or asthma No medical problems, no smoking, no complicated pregnancies, no seafood allergy; normal diet did not exceed two meals of fish per week; no preterm deliveries	Fish-oil supplement	20 weeks of pregnancy until delivery

Amount	Results	Conclusion*
Fish oil group: Four 1 g fish oil capsules/day 3.7 g of n-3 PUFA 56.0% as DHA and 27.7% as EPA	Neonatal in vitro IL-10 response to cat allergen was significantly lower in the fish oil group than in the placebo group (p=0.046). At birth, no significant differences were found in the neonates' cytokine response to allergens and mitogens in the two groups at birth.	B
Placebo group: Four 1 g olive oil capsules/day 66.6% n-9 oleic acid and <1.0% n-3 PUFA	IFN-≥ responses to OVA were detected more frequently in the control group than in the fish oil group (p=0.009). There were no significant differences found in the frequency of detectable IL-5, IL-10, or IL-13 responses between the two groups. "The detection of a lymphoproliferative response to allergens also tended to be lower in the fish oil group compared with the control group," although this difference was not always significant (OR=4.48, 95% CI 0.87-23.07 for response to OVA allergen and OR=2.02, 95% CI 0.69-5.88 for response to cat).	
Fish oil group: Four 1 g fish oil capsules/day 3.7 g of n-3 PUFA 56.0% as DHA and 27.7% as EPA	IL-13 levels were significantly lower (p=0.025) in neonates whose mothers received fish-oil supplements in pregnancy compared to the placebo group. There were no significant differences in IFN-≥ levels in cord plasmas or in IgE in plasma between the two groups.	B
Placebo group: Four 1 g olive oil capsules/day 66.6% n-9 oleic acid and <1.0% n-3 PUFA	There were no significant differences in the frequency of lymphocyte subsets for total T cells, T helper cells, T suppressor cells, NK cells, and B cells between the two groups. After adjusting for parity, gender, and delivery method, there were significant associations between cord plasma IL-13 levels and neonatal red cell membrane DHA levels (″=−0.25, 95% CI −0.49 to −0.01) and total n-3 fatty acid levels (″=−2.70, 95% CI −5.35 to −0.05).	

continued

TABLE B-1e Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Hawkes et al., 2002	Randomized Controlled Trial	Women (n=120) Aged 20-42 years, mean about 30 years Delivered full-term singleton infants, intended to breast-feed ε12 weeks Adelaide, South Australia No known history of inflammatory disorders, not currently taking anti-inflammatory medication or fish-oil supplements Excluded women who had ceased lactating by 4 weeks postpartum	DHA supplement	Day 3-week 12 postpartum

Amount	Results	Conclusion*
Asked to limit fish and seafood intake to a maximum of 1 meal/week Placebo: 500 mg placebo oil Low-DHA capsule group: 70 mg EPA/day, 300 mg DHA/day High-DHA capsule group: 140 mg EPA/day, 600 mg DHA/day	"There was no significant difference between the dietary groups in mean rank concentrations of IL-6 or TNF- ± in the aqueous phase of milk" at 4 weeks postpartum. "There was no significant difference in mean rank concentrations between the dietary groups for any of the cytokines produced by cells isolated from human milk or peripheral blood after in vitro stimulation with lipopolysaccharide or in the absence of stimulation" at 4 weeks postpartum.	N

continued

TABLE B-1e Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Hodge et al., 1998	Randomized Controlled Trial	Boys and girls (n=39) Aged 8-12 years Sydney, Australia Asthmatic with a history of episodic wheeze in the last 12 months, AHR to histamine	Omega-3 diet and omega-6 diet	6 months

Amount	Results	Conclusion*
Omega-3 diet group: Canola oil and canola-based margarines and salad dressings to replace usual oils and margarines Supplement capsules = 0.18 g EPA and 0.12 g DHA/capsule 4 capsules/day = 1.20 g omega-3/day Omega-6 diet group: Sunflower oil and sunflower oil-based margarines and salad dressings to replace usual oils and margarines Supplement capsules = 0.45 g safflower oil, 0.45 g palm oil, 0.10 g olive oil/capsule No EPA or DHA	"There was no significant change in spirometric function, dose-response ratio to histamine or asthma severity score at either 3 or 6 months in either group."	N

continued

TABLE B-1e Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Newson et al., 2004	Cohort	Children (n=1238 with cord blood fatty acid data and eczema at 18 to 30 months data; n=2945 with maternal blood fatty acid data and eczema data; n=2764 with maternal blood fatty acid data and wheezing data) Bristol, England Avon Longitudinal Study of Parents and Children (ALSPAC)	Cord blood and maternal blood red cell fatty acid analysis	20 weeks of pregnancy and at delivery

*B = Evidence of a benefit; N = Evidence of no association or no clear association.

Amount	Results	Conclusion*
Cord blood (percentages of total red blood cell membrane phospholipid): Medians: 0.02 ALA, 0.11 EPA, 0.22 DPA, 2.00 DHA, 4.65 LA, and 7.80 AA Maternal blood (percentages of total red blood cell membrane phospholipid): Medians: 0.14 ALA, 0.23 EPA, 0.60 DPA, 2.02 DHA, 11.46 LA, and 5.88 AA	After controlling for sex, gestational age at birth, birth weight, mother's age, education level, housing tenure, parity, ethnicity, smoking in pregnancy, maternal atopic disease, child's head circumference at birth, child's crown to heel length at birth, mother's BMI, breast-feeding in first 6 months, and day care use in first 6 months: All associations between fatty acid exposure (based on cord blood levels and maternal blood levels) and eczema at 18 to 30 months were found to be nonsignificant; All associations between fatty acid exposure (based on both cord blood levels and maternal blood levels) and wheezing at 30 to 42 months of age were found to be nonsignificant; LA:ALA levels in cord blood were significantly associ - ated with later-onset wheeze (OR=1.30, 95% CI 1.04-1.61), as was the ratio of ALA:sum of n-3 products (OR=0.86, 95% CI 0.75-0.99); and No other significant associations were found between fatty acid exposure and transient infant wheeze, later-onset wheeze, or persistent wheeze.	N

TABLE B-1f Studies on Visual Acuity: Effects on Infants Supplemented with Omega-3 Fatty Acids in Formula

Author	Study Type	Subjects	Exposure	Timing of Exposure
Simmer, 2005	Cochrane Review	9 Randomized Controlled Trials	LCPUFA-supplemented formula	
Gibson et al., 2001	Review	Randomized Controlled Trials (11 on preterm and 10 on term infants) Involving healthy preterm infants fed preterm formula Involving healthy term infants fed formulas from near birth Systematic literature review	DHA-supplemented formula	
Uauy et al., 2001	Review	Summary of Randomized Controlled Trials on preterm and term infants	LCPUFA-supplemented formula	

Amount	Results	Conclusion*
	"There is little evidence from randomized trials of LCPUFA supplementation to support the hypothesis that LCPUFA supplementation confers a benefit for visual or general development of term infants."	N
	"Minor effects on VEP acuity have been suggested, but appear unlikely when all studies are reviewed."	
	"Benefits of adding DHA to formulas (with or without AA) on VEP acuity have been reported in some studies, whereas other studies have failed to detect a benefit of LC-PUFA supplementation."	B
	There is evidence supporting "the view that dietary essential fatty acid supply affects visual development of preterm and term infants."	B

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
SanGiovanni et al., 2000a	Meta-analysis	Studies done in industrialized countries Healthy, term infants Randomized studies: DHA supplemented (n=114) DHA-free (n=87) Nonrandomized studies: Milk-fed/behavioral-based (n=117 at 2 months; n=148 at 4 months) Milk-fed/electrophysiological tasks (n=146 at 4 months) DHA-free/behavioral-based (n=174 at 2 months; n=113 at 4 months) DHA-free/electrophysiological tasks (n=108 at 4 months) All study designs: DHA-supplemented/behavioral-based at 2 months (n=219) DHA-supplemented/electrophysiological tasks at 4 months (n=265) DHA-free/behavioral-based at 2 months (n=86) DHA-free/electrophysiological tasks at 4 months (n=109)	DHA-supplemented formula	

Amount	Results	Conclusion*
	Based on behavioral tests of visual acuity, the randomized studies showed a significant difference in the estimates for those fed DHA-supplemented formula vs. those fed unsupplemented formula at 2 months of age (p δ0.0005). This difference was not significant at any other age presented. Based on behavioral tests of visual acuity, the non-randomized studies showed a significant difference in the estimates for those fed human milk vs. those fed unsupplemented formula at 2 months of age (p δ0.0005) and 4 months of age (p δ0.05). This difference was not significant at any other age presented. Based on electrophysiological tests of visual acuity, the randomized studies showed a significant difference in the estimates for those fed (DHA-supplemented) formula vs. those fed unsupplemented formula at 7 months of age (p δ0.05). This difference was not significant at any other age presented. Based on electrophysiological tests of visual acuity, the nonrandomized studies showed a significant difference in the estimates for those fed human milk vs. those fed unsupplemented formula at 4 months of age (p δ0.0005), 5 months of age (p δ0.05), and 7 months of age (p δ0.05). This difference was not significant at any other age presented.	B

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
SanGiovanni et al., 2000b	Meta-analysis	5 original papers (4 prospective trials) 4 review chapters Preterm infants Randomized studies: DHA-supplemented/behavioral-based (n=48 at 2 months; n=70 at 4 months) DHA-supplemented/VEP at 4 months (n=13) DHA-free/behavioral-based (n=49 at 2 months; n=56 at 4 months) DHA-free/VEP at 4 months (n=28) All study designs: DHA-supplemented/behavioral-based at 4 months (n=80) DHA-supplemented/VEP at 4 months (n=37) DHA-free/behavioral-based at 4 months (n=87) DHA-free/VEP at 4 months (n=43)	DHA-supplemented formula	

Amount	Results	Conclusion*
	Based on behavioral tests of visual acuity, the randomized comparisons (between those fed DHA-supplemented formula and those fed unsupplement - ed formula) showed significant differences at 2 and 4 months of age (p δ0.001). This difference was not significant at any other age presented.	B

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Hoffman et al., 2003	Randomized Controlled Trial	Infants (n=61) Healthy, term, singleton infants Birth weight appropriate for gestational age Breast-fed to 4-6 months North Dallas area, TX 95% White No family history of milk protein allergy; genetic or familial eye disease; vegetarian or vegan maternal dietary patterns; maternal metabolic disease, anemia, or infection; presence of a congenital malformation or infection; jaundice; perinatal asphyxia; meconium aspiration; or any perinatal event that resulted in placement in the neonatal intensive care unit	AA/DHA-supplemented formula	Enrolled at 6.5 weeks of age until 12 months of age (during time of weaning)

Amount	Results	Conclusion*
Commercial formula (Enfamil with iron) or commercial formula supplemented with 0.36% of total fatty acids as DHA and 0.72% as AA	There were no significant differences in VEP acuity before weaning in the two groups, but at 12 months the supplemented group had significantly better VEP acuity than infants in the commercial formula group ($p<0.0005$). There was a trend of better stereoacuity in the supplemented group compared to the commercial group at 9 months ($p=0.12$) and 12 months ($p=0.13$).	B

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Birch et al., 2002	Randomized Controlled Trial	Infants (n=65) Healthy, term, singleton births Birth weight appropriate for gestational age Weaned from breast-feeding at 6 weeks of age Dallas area, TX Mean maternal age about 30 years 75-78% White Majority of mothers with at least a college degree No family history of milk protein allergy; genetic or familial eye disease; vegetarian or vegan maternal dietary patterns; maternal metabolic disease, anemia, or infection; presence of a congenital malformation or infection; jaundice; perinatal asphyxia; meconium aspiration; or any perinatal event that resulted in placement in the neonatal intensive care unit	AA/DHA-supplemented formula	6 weeks of age to 52 weeks of age

Amount	Results	Conclusion*
Commercial formula (Enfamil with iron) or commercial formula supplemented with 0.36% of total fatty acids as DHA and 0.72% as AA	There were no significant differences in VEP acuity at age 6 weeks between the two groups. The control group had significantly poorer visual acuity at week 17 ($p < 0.003$), week 26 ($p < 0.001$), and week 52 ($p < 0.001$) compared to the supplemented group.	B

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Innis et al., 2002	Randomized Controlled Trial	Infants (n=194) Premature Healthy, very low birth weight infants (846-1560 g), formula-fed Multi-center study (16 neonatal centers in North America) Not small for gestational age or >24 days postnatal age when full enteral feeds ε375 kJ/kg/day were achieved No necrotizing enterocolitis or other gastrointestinal disease, impaired visual or ocular status, or a history of underlying disease or congenital malformation that could interfere with growth Reference group = term infants whose mothers anticipated breast-feeding for at least 4 months	AA/DHA-supplemented formula	Preterm formulas: At least 28 days after enteral intake of 375 kJ/kg/day reached Term formulas: After hospital discharge until 57 weeks of age

Amount	Results	Conclusion*
Preterm formula 1 = Control formula (no AA or DHA) Preterm formula 2 = DHA formula (0.34% fatty acids as DHA) Preterm formula 3 = DHA+AA formula (0.33% fatty acids as DHA, 0.60% fatty acids as AA) Term formula = no AA or DHA Breast-fed term infants = no solid foods during the study unless otherwise instructed by their physicians	At 57 weeks, visual acuity of the breast-fed term infants was significantly higher than in the prema - ture infants, but not at 48 weeks; at 48 or 57 weeks, visual acuity was not significantly different among the premature infant groups.	N

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Van Wezel-Meijler et al., 2002	Randomized Controlled Trial	Infants (n=42) Preterm, admitted to neonatal intensive- or high-care unit of hospital Birth weight <1750 g Leiden, Netherlands Mothers not breast-feeding Normal neurological examination throughout the neonatal period Repeated ultrasound of the brain being normal or showing, at most, minor abnormalities No abnormalities of the central nervous system; abnormal neurological examination or occurrence of seizures; any systemic disease with potential negative influence on future growth or development; serious nutritional or gastrointestinal problems preventing initiation of enteral feeding after the first week postpartum or complete enteral feeding after the third week postpartum; retinopathy of prematurity grade 3 or more	AA/DHA-supplemented formula	2-3 weeks after birth until weighing 3000 g

Amount	Results	Conclusion*
Supplemented preterm formula: 4.4 g fat/100 mL 0.015 g/100 mL of added DHA (microalgae) 0.031 g/100 mL of added AA (fungi) Control formula: 4.4 g fat/100 mL No addition of AA and DHA	There were no significant differences found in Flash VEP at 3 and 12 months between the two groups. There were no significant differences found in visual acuity at 3, 6, 12, or 24 months between the two groups.	N

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Makrides et al., 2000	Randomized Controlled Trial	Infants (n=73 in formula groups; n=63 in breast-fed group) White Full-term and appropriate weight for gestational age Mean mothers' education was mid-secondary school level for formula-fed infants and completion of secondary school for breast-fed infants No congenital disease or complications during pregnancy	AA/DHA-supplemented formula	Age at entry not specified, up to 34 weeks of age
Bougle et al., 1999	Randomized Controlled Trial	Infants (n=40) Mean age about 33 weeks Enrolled the 2nd day of enteral feeding Healthy, appropriate weight for gestational age Premature Free of respiratory, metabolic or neurological disease; malformations; infections; intrauterine asphyxia Fed by digestive route within the first 7 days of life	LCPUFA-supplemented formula	Within the first 2 days of enteral feeding, then for 30 days

Amount	Results	Conclusion*
Placebo formula (% total fatty acids): 16.8% LA, 1.5% ALA DHA formula (% total fatty acids): 16.80% LA, 1.20% ALA, 0.10% EPA, 0.35% DHA DHA+AA formula (% total fatty acids): 16.60% LA, 0.34% AA, 1.00% ALA, 0.34% DHA Breast milk (% total fatty acids, mean±SE): 13.40±2.90% LA, 0.39±0.07% AA, 0.95±0.32% ALA, 0.09±0.03% EPA, 0.20±0.07% DHA	After adjusting for gender, postconceptional age, birth weight, and maternal smoking, there were no significant differences in VEP between any of the groups at 16 or 34 weeks of age.	N
Breast milk (% total fatty acids, mean±SE): 14.1±2.0% LA, 0.4±0.2% GLA, 0.9±0.2% AA, 0.5±0.1% ALA, 0.5±0.1% DHA Formula A (% total fatty acids): 14.1% LA, 1.3% ALA Formula B (% total fatty acids): 17.7% LA, 0.4% GLA, 0.1% AA, 1.2% ALA, 0.1% EPA, 0.6% DHA	There were no significant differences between the groups based on electrophysiological data, except that the maturation of the motor nerve conduction was significantly slower in the Formula B group than in the breast milk group and the Formula A group ($p<0.05$).	N

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Carlson et al., 1999	Randomized Controlled Trial	Infants (n=119)	AA/DHA-supplemented formula	<8 days of age until about 12 months of age Infants fed supplemented formula near birth received commercial formula from term less 3 months until 12 months of age; infants fed supplemented formula near term received commercial formula from term less 3 months to term less 1 month, and then supplemented formula until 12 months of age

Amount	Results	Conclusion*
Commercially available standard formula contained no EPA or DHA	Compared to the infants not supplemented, "only those supplemented near birth had higher acuity at 2 months ($p<0.02$) and a trend toward higher acuity at 6 months ($p<0.07$)."	B
Supplemented formula 0.13% DHA and 0.40% AA from egg phospholipids	Infants supplemented at birth "also had higher acuity than those supplemented at term at 2 months ($p<0.05$)." "First year acuity continued to increase ($p<0.05$) between consecutive ages until 6 months" in those supplemented at birth and 9 months in those un-supplemented and supplemented at term. "All groups had similar acuity at 9 and 12 months."	

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Birch et al., 1998	Randomized Controlled Trial	Infants (n=108) Healthy, term, birth weight appropriate for gestational age Singleton births Dallas, TX 75% White, 12% Black, 12% Hispanic, 1% other Mean maternal age 29 years 67.6% mothers completed at least 2 years of college No family history of milk protein allergy; genetic or familial eye disease; vegetarian or vegan maternal dietary patterns; maternal metabolic disease, anemia, or infection; presence of a congenital malformation or infection; jaundice; perinatal asphyxia; meconium aspiration; or any perinatal event that resulted in placement in the neonatal intensive care unit	AA/DHA-enriched formula	0-4 days postpartum through 17 weeks of age
Carlson et al., 1996a	Randomized Controlled Trial	Infants (n=58) Born at term (37-43 weeks) Birth weight 747-1275 g Memphis, TN Predominantly Black No growth retardation in utero and no medical problems likely to influence long-term growth and development Mothers education mean of about 12 years	DHA-supplemented formula	24 hours after birth; end point not specified

Amount	Results	Conclusion*
Enfamil + iron Enfamil + iron + 0.35% DHA Enfamil + iron + 0.36% DHA + 0.72% AA	Visual acuity was significantly poorer in the control group than in the DHA or DHA+AA groups and the breast-fed group. At 6, 17, 26, and 52 weeks the association between RBC AA and sweep VEP was not statistically significant. The association was also nonsignificant for RBC EPA. At 6, 17, 26, and 52 weeks, the association between RBC DHA was significantly associated with lower sweep VEP ($p<0.001$, $p=0.01$, $p=0.05$, $p<0.001$, respectively). At 6, 17, and 52 weeks, the association between RBC n-3:n-6 was significantly associated with lower sweep VEP ($p<0.001$, $p=0.03$, $p<0.001$, respectively); the association was not statistically significant at 26 weeks.	B
Formula with AA+DHA = 2 g AA/100 g total fatty acids; 0.1 g DHA/100 g total fatty acids Formula without DHA = 2.2 g ALA/100 g total fatty acids	"Term infants fed formulas with added AA and DHA had higher grating acuity at 2 months of age but not at 4, 6, 9, or 12 months of age compared with infants fed an unsupplemented formula."	B

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Carlson et al., 1996b	Randomized Controlled Trial	Infants (n=59) Memphis, TN Maternal mean age about 22.5 year No intraventricular or periventricular hemorrhage > grade 2; a history of maternal cocaine or alcohol abuse; congenital anomalies likely to affect long-term growth and development; or intrauterine growth retardation Full enteral feeding of 418 kJ/kg/day by 6 weeks of age and tolerated enteral feeding thereafter	EPA/DHA-supplemented formula (marine oil)	Between 3-5 days post-partum until 2 months from expected term of 48±1 week post-menstrual age
Carlson et al., 1993	Randomized Controlled Trial	Infants (n=67) Birth weight 748-1398 g Mean gestational age 29 weeks Memphis, TN Did not require mechanical ventilation; have intraventricular hemorrhage > grade 2; have retinopathy of prematurity > stage 2; require surgical intervention for necrotizing enterocolitis; have severe intrauterine growth retardation; or a history of maternal substance abuse Predominantly Black and from lower socioeconomic groups Maternal age about 23 years	EPA/DHA-supplemented formula (marine oil)	Preterm formula from when infant tolerated enteral intakes >462 kJ/kg body weight/day for 5-7 days (H3 weeks of age) until discharge Term formula from discharge until 9 months

Amount	Results	Conclusion*
Standard preterm formula = LA at 2.5% of total fatty acid Marine-oil supplemented formula = 0.20% DHA and 0.06% EPA of total fatty acids	"Visual acuity improved significantly between successive ages of 0 and 2 months, 2 and 4 months . . . Between 6 and 12 months visual acuity plateaued."	B
Commercially available standard formula contained no EPA or DHA Marine-oil supplemented formula contained 0.2% DHA and 0.3% EPA of total fatty acids	Visual acuity development was significantly higher in the marine-oil group compared to the control group at 2 months ($p<0.014$) and 4 months ($p<0.002$). There were no significant differences found at the other ages reported.	B

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Birch et al., 1992	Randomized Controlled Trial	Male infants (n=32) Female infants (n=41) Born 27-33 weeks gestation Birth weight 1000-1500 g No respirator treatment for more than 7 days or congenital infections; gross congenital malformations; retinopathy of prematurity; or grade III or IV intracranial hemorrhages	EPA/DHA-supplemented formula (soy/marine oil)	10 days of age until 6 months of age
Lauritzen et al., 2001	Review	Summary of the literature (animal, observational, RCTs)	DHA-supplemented formula	

Amount	Results	Conclusion*
Soy/marine oil-supplemented formula (preterm/follow-up formula, g/100 g lipids): LA = 20.4/18.1 ALA = 1.4/1.4 EPA+DHA = 1.0/0.9 Corn oil-based formula (preterm/follow-up formula, g/100 g lipids): LA = 24.2/21.1 ALA = 0.5/0.5 EPA+DHA = 0.0/0.0 Soy oil-based formula (preterm/follow-up formula, g/100 g lipids): LA = 20.8/20.3 ALA = 2.7/2.8 EPA+DHA = 0.0/0.1	There were significant differences in VEP acuity for the different formula groups ($p < 0.025$), with the corn oil group having poorer VEP acuity than the soy/marine oil group ($p < 0.05$) at 36 weeks. The corn oil group ($p < 0.05$) and the soy oil group ($p < 0.05$) had significantly poorer VEP acuity than the soy/marine oil group at 57 weeks.	B
	"Observational studies in general show better retinal function in breast-fed infants than in infants fed formula without DHA, but approximately half of the intervention studies show no effect." Animal studies do offer evidence that DHA plays a role in retinal function, but these results cannot eas - ily be extrapolated to humans. 4 RCTs with "preterm infants have all shown a posi - tive effect of dietary DHA on visual development;" the results from term infants are not as conclusive. More data is needed to see if the "variation in DHA content of human milk has a functional effect."	B

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Williams et al., 2001	Cohort	Boys and girls (n=435) Mean age of 3.5 years Born in last 6 months of the Avon Longitudinal Study of Parents and Children (ALSPAC) enrollment period Healthy term infants	Seafood (mother) and breast milk (child)	Seafood = during pregnancy (mother) Breast milk = until 4 months of age (child)

Amount	Results	Conclusion*
Oily fish consumption categories: 1 = Never or rarely 2 = Once every 2 weeks 3 = More than once every 2 weeks White fish = cod, haddock, plaice, and "fish fingers" Oily fish = pilchards, sardines, mackerel, tuna, herring, kippers, trout, and salmon	After adjusting for breast-feeding, sex, maternal education, maternal age, housing tenure, financial difficulties, maternal smoking, number of older siblings in household, child care, maternal job status, mother being vegetarian, mother's fish-eating habits: "Mothers who ate oily fish at least once every 2 weeks during pregnancy were more likely to have children who achieved foveal stereoacuity than were the mothers who never ate oily fish (OR=1.57, 95% CI 1.00-2.45)," but this was not significant; and "The results of this study suggest that for full-term infants, breast-feeding is associated with enhanced stereopsis at age 3.5 years, as is a maternal DHA-rich antenatal diet, irrespective of later infant feeding practice."	B

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Carlson et al., 1986	Cohort	Infants (n=27) Born on or before 32 weeks gestation (range 24-32 weeks) University of Mississippi Medical Center Weighed <1500 g at birth and were on full feedings of at least 60 kcal/kg without intravenous supplementation Free of major congenital malformations and did not have any ongoing major disease process Discharged at about 1800 g	Human milk and milk formula	Delivery to an average of 7 weeks later

Amount	Results	Conclusion*
Expressed, previously frozen milk produced by their own mothers or formula	Based on phosphatidylethanolamine composition of fatty acids (in mol%): EPA was significantly lower ($p<0.005$) in those breast-fed after the feedings than in the pre-study samples; LA and DPA were significantly higher ($p<0.001$) and DHA was significantly lower ($p<0.005$) in those breast-fed after the feedings than in the preterm cord blood; LA was significantly higher ($p<0.005$) and EPA was significantly lower ($p<0.005$) in those formula-fed after the feedings than in the pre-study samples; LA was significantly higher ($p<0.005$) and DHA was significantly lower ($p<0.001$) in those formula-fed compared to those breast-fed; LA ($p<0.005$) and DPA ($p<0.001$) were significantly higher and AA ($p<0.005$) and DHA ($p<0.001$) were significantly lower in those formula-fed after the feedings than in the preterm cord blood; LA was significantly higher ($p<0.005$) and EPA was significantly lower ($p<0.005$) in those formula-fed after the feedings than in the pre-study samples.	N/A
Infants fed formula started with enteral feeding with Portagen and then Enfamil Premature and Similac Special Care as tolerated. Those followed after discharge were fed term formulas also produced by Enfamil and Similac		
Human milk (in mol%, mean±SE): LA = 16.00±1.30, AA = 0.59±0.04, ALA = 0.62±0.04, EPA = 0.03±0.00, DPA = 0.09±0.03, DHA = 0.19±0.03	Based on phosphatidylcholine composition of fatty acids (in mol%): LA was significantly higher ($p<0.005$) in those breast-fed after the feedings than in the pre-study samples; LA was significantly higher ($p<0.005$) and AA ($p<0.001$) and DHA ($p<0.005$) were significantly lower in those breast-fed after the feedings than in the preterm cord blood; LA was significantly higher ($p<0.001$) and AA was significantly lower ($p<0.001$) in those formula-fed after the feedings than in the pre-study samples; LA was significantly higher ($p<0.005$) and AA and DHA were significantly lower ($p<0.001$) in those formula-fed compared to those breast-fed; LA was significantly higher ($p<0.005$) and AA and DHA were significantly lower ($p<0.001$) in those formula-fed after the feedings than in the preterm cord blood.	
Portagen (in mol%, mean±SE): LA = 8.1, AA = None, ALA = Trace, EPA = None, DPA = None, DHA = None		
Enfamil Premature (in mol%, mean±SE): LA = 22.4, AA = None, ALA = 0.6, EPA = None, DPA = None, DHA = None	Based on phosphatidylserine composition of fatty acids (in mol%): LA and DHA were significantly higher ($p<0.005$) in those breast-fed after the feedings than in the preterm cord blood; AA was significantly lower ($p<0.005$) in those breast-fed after the feedings than in the pre-study samples; LA and DHA were significantly higher ($p<0.005$) in those formula-fed after the feedings than in the pre-study samples; AA was significantly lower ($p<0.005$) and DHA was significantly higher ($p<0.025$) in those formula-fed after the feedings than in the pre-study samples.	
Similac Special Care (in mol%, mean±SE): LA = 17.4, AA = None, ALA = 0.9, EPA = None, DPA = None, DHA = None		

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Putnam et al., 1982	Cohort	Infants (n=40) Enrolled at birth Well-baby clinic at the University of South Florida Medical Clinics At least 90% of energy from human milk or formula before sample collection	Human milk and milk formula	3 weeks of age to 6 months of age Breast milk collected at 8 weeks and infants' blood drawn between 4.5 and 6 months of age

Amount	Results	Conclusion*
Mothers were encouraged to follow the recommendations of the American Academy of Pediatrics Committee on Nutrition (food other than human milk or humanized formula be omitted from infant's diet until he/she was 4-6 months of age) Human milk (% of total, mean): 15.80±0.61 LA, 0.60±0.03 AA, 0.80±0.09 ALA, 0.10±0.03 EPA, 0.10±0.01 DPA, 0.10±0.01 DHA Enfamil + iron (% of total, mean): 45.1 LA, No AA, 5.0 ALA, No EPA, No DPA, No DHA SMA formula (% of total, mean): 14.0 LA, No AA, 1.2 ALA, No EPA, No DPA, No DHA	"Human milk-fed infants had lower concentrations of membrane LA than SMA-fed infants despite the equivalent relative intakes of dietary LA." "These diets did not influence the relative contributions of PE, PC, Sp, and PS to erythrocyte membrane phospholipid nor did they influence the lipid phosphorous/cholesterol ratio." Significant differences in fatty acid composition of infant erythrocyte ethanolamine are as follows (weight % of total fatty acid methyl esters): Infants fed human milk had significantly higher AA ($p<0.05$), DPA ($p<0.05$), and DHA ($p<0.001$) than those fed SMA formula; and Infants fed human milk had significantly higher AA ($p<0.01$) and significantly lower LA ($p<0.001$), ALA ($p<0.001$), EPA ($p<0.05$), and DHA ($p<0.001$) than those fed Enfamil formula with iron.	N/A

continued

TABLE B-1f Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Sanders and Naismith, 1979	Cross-sectional	Infants (n=18) Aged 14 weeks Fed from birth a modified cow's milk formula or had been breast-fed Participated in an earlier study	Human milk and milk formula	14 weeks of age
Neuringer et al., 1984	Animal	Adult female rhesus monkeys	Diet deficient in n-3 fatty acids	2 months before conception and throughout pregnancy

*N = Evidence of no association or no clear association; B = Evidence of a benefit; N/A = A conclusion is not available; these data are presented for background information only.

Amount	Results	Conclusion*
Breast milk (% total fatty acids, mean±SE): LA = 6.90±0.81, ALA = 0.80±0.05, EPA = 0.20±0.08, DPA = 0.52±0.27, DHA = 0.59±0.23 Milk formula (% total fatty acids, mean): LA = 1.60, ALA = 0.70, EPA = 0.08, DPA = 0.11, DHA = 0.02	LA, AA, DHA are significantly lower in the formula-fed infants than in the breast-fed infants ($p < 0.01$, $p < 0.05$, $p < 0.01$, respectively). EPA and DPA are significantly higher in the formula-fed infants than in the breast-fed infants ($p < 0.05$). "The minimum requirement of the young infant for LA is substantially less than 1% of the dietary energy, the value most widely quoted."	N/A
Experimental group: Semipurified diet deficient in n-3 fatty acids Safflower oil sole fat source 76.0% LA, 0.3% GLA, 0.2% DGLA, 0.3% ALA, 225.0% n-6:n-3 of total fatty acids Control group: Soy bean oil sole fat source 53.1% LA, 0.0% GLA, 0.3% DGLA, 7.7% ALA, 7.0% n-6:n-3 of total fatty acids	AA and total n-6 fatty acids were significantly higher in the experimental group infants compared to the control group infants ($p < 0.005$). ALA, EPA, DPA, DHA and total n-3 fatty acids are all significantly lower in the experimental group infants compared to the control group infants ($p < 0.001$). At 4, 8, and 12 weeks, the visual acuity threshold in the experimental group was significantly lower than in the control group ($p < 0.05$, $p < 0.0005$, $p < 0.005$, respectively).	B

TABLE B-1g Studies on Cognitive and Motor Development: Effects on Infants Supplemented with Omega-3 Fatty Acids in Formula

Author	Study Type	Subjects	Exposure	Timing of Exposure
Cohen et al., 2005	Review	Aggregated 8 randomized controlled trials (1 study of maternal dietary supplementation and 7 studies of formula supplementation)	n-3 supplement	
Simmer and Patole, 2005	Cochrane Review	11 randomized controlled trials	LCPUFA-supplemented formula	
Simmer, 2005	Cochrane Review	9 randomized controlled trials	LCPUFA-supplemented formula	

Amount	Results	Conclusion*
	An increase in maternal intake of DHA during pregnancy of 1 g/day will increase child IQ by 0.8-1.8 points.	B
	"Prenatal maternal DHA intake increasing the child plasma (RBC) DHA phospholipid fraction by 1% has the same impact on cognitive development as formula DHA supplementation that increases the child's plasma (RBC) DHA phospholipid fraction by 1%."	
	"Because typical DHA intake associated with fish consumption is well under 1 g/day, changes in fish consumption will result in IQ effects amounting to a fraction of a point," but they are not clinically detectable.	
	"No long-term benefits were demonstrated for infants receiving formula supplemented with LCPUFA. There was no evidence that supplementation of formula with n-3 and n-6 LCPUFA impaired the growth of preterm infants."	N
	"There is little evidence from randomized trials of LCPUFA supplementation to support the hypothesis that LCPUFA supplementation confers a benefit for visual or general development of term infants."	N
	"Minor effects on VEP acuity have been suggested, but appear unlikely when all studies are reviewed."	

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Gibson et al., 2001	Review	Randomized controlled trials (11 on preterm and 10 on term infants) Involving healthy preterm infants fed preterm formula Involving healthy term infants fed formulas from near birth Systematic literature review	LCPUFA-supplemented formula	
Uauy et al., 2001	Review	Summary of randomized controlled trials on preterm and term infants	AA/DHA-supplemented formula	
Carlson and Neuringer, 1999	Review	Summary of animal studies and randomized controlled trials Based on a session from the AOCS 1996 meeting: *PUFA in Infant Nutrition: Consensus and Controversies*	Neural DHA accumulation	

Amount	Results	Conclusion*
	"Although there are still some concerns on safety issues regarding the addition of LCPUFA to preterm infant formula, the evidence in support of a beneficial effect of such supplementation on visual function is relatively compelling."	B
	"It seems that the possible negative effects of n-3 LCPUFA on growth of preterm infants have been overcome through improved study design and/or the addition of a balance of n-6 and n-3 LCPUFA."	
	"There is also mixed evidence for the support of an effect of dietary LCPUFA on more global measures of development (Bayley's Scales of Infant Development or Brunet-Lezine test)."	
	"Evidence for a beneficial effect of AA+DHA supplementation on CNS development is strong."	B
	"The preliminary information on cognitive development is insufficient to fully establish a relationship between LCPUFA and mental development."	
	Studies in deficient monkeys suggest that "lower brain accumulation of DHA may influence neural domains such as sensation, motivation or temperament, but not cognition."	B
	"The most consistent effect identified to date in human and animal studies has been that of look duration and tests of visual attention."	
	"A limited number of behavioral studies in animals and humans address the question of neural DHA accumulation and developmental measures other than vision."	

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Bouwstra et al., 2005	Randomized Controlled Trial	Infants (n=256 to 446, depending on assessment) Term, healthy Groningen, Netherlands University and Martini Hospitals in Groningen and at midwife clinics No congenital disorders that interfered with adequate functioning in daily life; infants from multiple births; infants whose mothers did not have mastery of the Dutch language or suffered from significant illness or disability; adopted or foster infants; or formula-fed infants who had received human milk >5 days	LCPUFA-supplemented formula	Birth to 2 months of age

Amount	Results	Conclusion*
Control formula (in mol%): 11.56 LA, 1.27 ALA Supplemented formula (in mol%): 11.00 LA, 0.18 GLA, 0.03 DGLA, 0.39 AA, 1.30 ALA, 0.06 EPA, 0.23 DHA Breastfed (in mol%, mean±SE): 13.62±4.24 LA, 0.11±0.03 GLA, 0.34±0.06 DGLA, 0.34±0.06 AA, 1.11±0.35 ALA, 0.06±0.04 EPA, 0.19±0.11 DHA	"The groups did not show statistically significant differences in clinical neurological condition, neurological optimality score, fluency score, and the psychomotor and mental development indices at 18 months."	N

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Clandinin et al., 2005	Randomized Controlled Trial	Infants (n=361) Preterm Multi-site study First phase: Gestational age δ35 weeks postmenstrual age <10 total days of enteral feeding of >30 mL/kg/day No congenital abnormalities of the gastrointestinal tract, hepatitis, hepatic or biliary pathology, necrotizing enterocolitis confirmed before enrollment, or history of underlying disease or congenital malformations likely to interfere with evaluation Second phase: Successful completion of the first phase, ε80% of enteral intake from study formula during hospitalization, and 100% caloric intake from study formula at completion of the first phase	Algal-DHA- and fish-DHA-supplemented formulas, human milk	Premature formula: ε14 days of age until at/near hospital discharge (40 weeks of age) Discharge formula: 40 weeks until 53 weeks postmenstrual age Term formula: 53 weeks until 92 weeks postmenstrual age

Amount	Results	Conclusion*
Control formula: No DHA or AA Algal-DHA formula: 17 mg DHA/100 kcal from algal oil, 34 mg AA/100 kcal from fungal oil 0.3% fatty acids from DHA, 0.6% fatty acids from AA Fish-DHA formula: 17 mg DHA/100 kcal from tuna fish oil, 34 mg AA/100 kcal from fungal oil 0.3% fatty acids from DHA, 0.6% fatty acids from AA Worldwide human milk: 0.3% DHA and 0.6% AA (weight of fatty acids)	At 118 weeks, breast-fed term infants had significantly higher MDI and PDI scores compared to the control formula group, the algal-DHA formula group, and the fish-DHA formula group ($p < 0.05$). At 118 weeks, the algal-DHA formula group had a higher MDI score ($p=0.056$), although it was not significant, and a significantly higher PDI score ($p<0.05$) compared to the control formula group. At 118 weeks, the fish-DHA formula group had significantly higher MDI and PDI scores ($p < 0.05$) compared to the control formula group.	B

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Jensen et al., 2005	Randomized Controlled Trial	Pregnant women (n=227) Aged 18-40 years Houston, TX White (75% DHA group; 79% control group) African American (19% DHA group; 13% control group) Women plan to breast-feed exclusively for ε4 months Infant gestational age >37 weeks Infant birth weight 2500-4200 g No chronic maternal disorders; major congenital anomalies and obvious gastrointestinal or metabolic disorders of the infant	DHA supplement	Within 5 days after delivery until 4 months postpartum
Fewtrell et al., 2004	Randomized Controlled Trial	Infants (n=238) Preterm Glasgow, UK Birth weight δ2000 g Mean maternal age about 29 years Social class 1 or 2 (18% in controls; 27% in LCPUFA group) Mothers with degree or higher (2% in controls; 7% in LCPUFA group)	LCPUFA-supplemented formula	Preterm formulas: when pediatrician decided that preterm formula should be started, to discharge Discharge formulas: from discharge until 9 months after term

Amount	Results	Conclusion*
High-DHA capsule (algal triacylglycerol): 0.8% LA and 41.7% DHA by weight 200 mg DHA/day Control capsule (soy and corn oil): 56.3% LA, 3.9% ALA by weight	There were no significant differences in visual acuity from the Teller Acuity Card at 4 or 8 months of age or from the Sweep VEP at 4 months of age between the two groups. There were no significant differences in mean transient VEP latency at 4 and 8 months of age between the two groups; but the transient VEP amplitude was significantly lower in the infants of the high-DHA capsule group compared to the infants of the control capsule group ($p < 0.03$). There were no significant differences in Gesell Gross Motor, CAT, or CLAMS DQ scores at 12 and 30 months of age or in Bayley MDI at 30 months of age between the two groups; but Bayley PDI at 30 months of age was 8.4 points higher in infants of the high-DHA capsule group compared to infants of the control capsule group.	N
LCPUFA-supplemented formulas (g/100 g fat): 12.30 LA, 0.04 AA, 1.50 ALA, 0.10 EPA, 0.50 DHA Control formulas (g/100 g fat): 11.5 LA, 1.6 ALA, no AA, EPA, or DHA	At 18 months of age, the Bayley MDI and PDI scores did not differ significantly between the groups. At 9 months of age, overall development scores and individual subscale scores did not differ significantly between the groups.	N

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Bouwstra et al., 2003	Randomized Controlled Trial	Infants (n=397) Term, healthy Groningen, Netherlands University and Martini Hospitals in Groningen and at midwife clinics No congenital disorders that interfered with adequate functioning in daily life; infants from multiple births; infants whose mothers did not have mastery of the Dutch language or suffered from significant illness or disability; adopted or foster infants; or formula-fed infants who had received human milk >5 days	LCPUFA-supplemented formula	Birth to 2 months of age

Amount	Results	Conclusion*
Control formula (in mol%): 11.56 LA, 1.27 ALA Supplemented formula (in mol%): 11.00 LA, 0.18 GLA, 0.03 DGLA, 0.39 AA, 1.30 ALA, 0.06 EPA, 0.23 DHA Breast-fed (in mol%, mean±SE): 13.62±4.24 LA, 0.11±0.03 GLA, 0.34±0.06 DGLA, 0.34±0.06 AA, 1.11±0.35 ALA, 0.06±0.04 EPA, 0.19±0.11 DHA	After controlling for profession of mother's partner requiring a university or vocational-college education, Obstetrical Optimality Score, and age at assessment: The control formula group had a significantly lower OR of occurrence of normal-optimal general movements at age 3 months when compared to the breast-fed infants (OR=0.55; p=0.038); and Those in the supplemented formula group had a significantly lower OR of occurrence of normal-optimal general movements at age 3 months when compared to the breast-fed infants (OR=0.42; p=0.006), but the OR was not significant when compared to the control formula group (OR=0.77; p=0.41). After controlling for marital status, family history of diabetes, gestational age at birth, condition of perineum, and age at assessment: The control formula group had a significantly higher OR of mildly abnormal general movements at age 3 months when compared to the breast-fed infants (OR=2.03; p=0.039); and The supplemented formula group had a significantly lower OR of mildly abnormal general movements at age 3 months when compared to the control formula group (OR=0.49; p=0.032), but the OR was not significant when compared to the breast-fed infants (OR=0.94; p=0.87).	B

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Helland et al., 2003	Randomized Controlled Trial	Pregnant women (n=48 in cod-liver oil group; n=36 in corn oil group) Aged 19-35 years Oslo, Norway Healthy women with, singleton pregnancy, nulli- or primiparous, intention to breast-feed No supplement of n-3 LCPUFA earlier during pregnancy, premature births, birth asphyxia, general infections, or anomalies in the infants that required special attention	Cod-liver oil supplement	From 18 weeks of pregnancy until 3 months after delivery
Fewtrell et al., 2002	Randomized Controlled Trial	Infants (n=195 formula-fed; n=88 breast-fed) Preterm Birth weight <1750 g Nottingham and Leicester, UK No congenital malformation known to affect neurodevelopment Mothers decided not to breast-feed by 10 days of age; tolerated enteral feeds at that time (for randomized groups) Social class 1 or 2 (19% in controls; 26% in LCPUFA group; 33% in breast-fed group)	LCPUFA-supplemented formula	10 days of age until discharge

Amount	Results	Conclusion*
Cod-liver oil: 10 mL/day 1183 mg DHA, 803 mg EPA Corn oil: 10 mL/day 4747 mg LA, 92 mg ALA	K-ABC scores were significantly higher for the subset MPCOMP among children from the cod-liver oil group compared to the corn oil group (p=0.049). The scores for the other subtests (SEQPROC, SIMPROC, NONVERB) were also higher in the cod-liver oil group compared to the corn oil group, but they were not significant.	B
LCPUFA-supplemented formula (g/100 g fat): 12.00 LA, 0.31 AA, 0.60 ALA, 0.04 EPA, 0.17 DHA Control formula (g/100 g fat): 10.6 LA, 0.7 ALA, no detected AA, EPA, DHA	There were no significant differences in KPS quotients at 9 months of age and neurological status at 9 or 18 months of age between the two formula groups. There were no significant differences found in Bayley MDI or PDI at 18 months of age between the two formula groups. Breast-fed infants had significantly higher KPS quotients (overall, adaptive, gross motor, fine motor, and personal-social) at 9 months of age ($p < 0.005$) and significantly higher Bayley MDI and PDI at 18 months of age ($p < 0.005$) compared to the control formula-fed infants. Breast-fed infants had significantly higher KPS quotients (overall, adaptive, gross motor, fine motor, and personal-social) at 9 months of age ($p < 0.005$; $p < 0.05$ for gross motor quotient) and significantly higher Bayley MDI and PDI at 18 months of age ($p < 0.005$) compared to the LCPUFA-supplemented formula infants.	N

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Van Wezel-Meijler et al., 2002	Randomized Controlled Trial	Infants (n=42) Preterm, admitted to neonatal intensive- or high-care unit of hospital Birth weight <1750 g Leiden, Netherlands Mothers not breast-feeding Normal neurological examination throughout the neonatal period Repeated ultrasound of the brain being normal or showing, at most, minor abnormalities No abnormalities of the central nervous system; abnormal neurological examination or occurrence of seizures; any systemic disease with potential negative influence on future growth or development; serious nutritional or gastrointestinal problems preventing initiation of enteral feeding after the first week postpartum or complete enteral feeding after the third week postpartum; retinopathy of prematurity grade 3 or more	AA/DHA-supplemented formula	2-3 weeks after birth until weighing 3000 g

Amount	Results	Conclusion*
Supplemented pre-term formula: 4.4 g fat/100 mL 0.015 g/100 mL of added DHA (microalgae) 0.031 g/100 mL of added AA (fungi) Control formula: 4.4 g fat/100 mL No addition of DHA and AA	There were no significant differences found in Bayley MDI and PDI at 3, 6, 12, or 24 months between the two groups. There were no significant differences found in myelination at 3 and 12 months between the two groups.	N

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Auestad et al., 2001	Randomized Controlled Trial	Infants (n=294 formula-fed; n=165 breast-fed) Kansas City, MO; Little Rock, AR; Pittsburgh, PA; Tucson, AZ Good health, term status, either δ9 days of age (formula group) or δ11 days of age and currently breast-feeding (breast-feeding group), birth weight ε2500 g, 5-minute APGAR score ε7, ability to tolerate milk-based formula or breast milk, guardian or parent agreement to feed the assigned study formula ad libitum according to the study design No evidence of significant cardiac, respiratory, ophthalmologic, gastrointestinal, hematologic, or metabolic disease; milk-protein allergy; or a maternal medical history known to have proven adverse effects on the fetus, tuberculosis, HIV, perinatal infections, or substance abuse 61-74% European American 60-80% mothers married Mean mothers' age about 29 years Mean mothers' education about 14 years	Fish oil/fungal oil and egg-derived triglyceride-supplemented formulas	9-11 days after birth until 12 months of age

Amount	Results	Conclusion*
Fish oil and fungal oil-supplemented preterm formula: 0.46 g AA/100 g total fatty acids δ0.04 g EPA/100 g total fatty acids 0.13 g DHA/100 g total fatty acids Egg-derived triglyceride-supplemented preterm formula: 0.45 g AA/100 g total fatty acids No detected EPA 0.14 g DHA/100 g total fatty acids Control formula: No detected AA, EPA, DHA	The vocabulary expression score at 14 months was significantly higher in the fish/fungal group than in the egg-TG group ($p<0.05$). Smiling and laughter was significantly higher in the control group than in the egg-TG group ($p=0.05$). No other development, cognition, vocabulary, or temperament outcomes presented were significantly different between the formula groups.	B

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
O'Connor et al., 2001	Randomized Controlled Trial	Infants (n=470) Preterm Birth weight 750-1800 g Cleveland, OH; Kansas City, MO; Little Rock, AR; Nottingham and Leeds, UK; Louisville, KY; Portland, OR; New York, NY; Santiago, Chile White (n=81 controls; n=80 fish/fungal; n=85 egg-TG) No serious congenital abnormalities that could affect growth and development; major surgery before randomization; periventricular/intraventricular hemorrhage greater than grade II; maternal incapacity; liquid ventilation; asphyxia resulting in severe and permanent neurologic damage; or uncontrolled systemic infection at the time of enrollment	Fish oil/fungal oil and egg-derived triglyceride/fish oil-supplemented formulas	In hospital formula from within 72 hours of first enteral feeding until term-corrected age Post-discharge formula from term-corrected age until 12 months of age

Amount	Results	Conclusion*
All in g/100 g total fatty acids (mean±SE) In-hospital control: 16.0±0.9 LA, 2.4±0.1 ALA, no AA, EPA, DHA In-hospital AA+DHA (fish/fungal oil): 16.80±1.00 LA, 2.60±0.30 ALA, 0.43±0.02 AA, 0.08±0.01 EPA, 0.27±0.04 DHA In-hospital AA+DHA (egg-TG/fish oil): 17.50±0.90 LA, 2.50±0.30 ALA, 0.41±0.00 AA, no EPA, 0.24±0.01 DHA Post-discharge control: 19.1±1.1 LA, 2.4±0.2 ALA, no AA, EPA, DHA Post-discharge AA+DHA (fish/fungal oil): 19.50±0.70 LA, 2.40±0.20 ALA, 0.43±0.01 AA, no EPA, 0.16±0.01 DHA Post-discharge AA+DHA (egg-TG/fish oil): 20.30±0.40 LA, 2.40±0.20 ALA, 0.41±0.02 AA, no EPA, 0.15±0.02 DHA	The mean novelty preference of the egg-TG/fish oil formula group was significantly greater than the control group (p=0.02) and the fish/fungal formula group (p=0.003) at 6 months corrected age. Using a Bonferroni adjusted alpha level of 0.0083, the difference between the fish/fungal formula group and the egg-TG/fish formula group was statistically significant. "Vocabulary comprehension did not differ among the 3 study formula groups at either 9 or 14 months corrected age in either the intent-to-treat or sub-group analysis."	B

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Birch et al., 2000	Randomized Controlled Trial	Infants (n=56) Healthy, term, birth weight appropriate for gestational age Singleton births Dallas, TX Predominantly White About 65% mothers had a college or postgraduate education No family history of milk protein allergy; genetic or familial eye disease; vegetarian or vegan maternal dietary patterns; maternal metabolic disease, anemia; or infection; presence of a congenital malformation or infection; jaundice; perinatal asphyxia; meconium aspiration; or any perinatal event that resulted in placement in the neonatal intensive care unit	AA-enriched formula	0-4 days of age to 17 weeks of age
Lucas et al., 1999	Randomized Controlled Trial	Infants (n=309 formula-fed; n=138 breast-fed) Healthy, term, singleton pregnancies, appropriate size for gestational age Nottingham and Leicester, UK Mean maternal age about 27 years 93.5% married About 70% with no higher school qualifications	LCPUFA-supplemented formula	Birth until 6 months of age

Amount	Results	Conclusion*
Enfamil + iron Enfamil + iron + 0.35% DHA Enfamil + iron + 0.36% DHA + 0.72% AA	The mean Bayley MDI score at 18 months was significantly higher in the DHA/AA-supplemented formula group than in the control formula group ($p<0.05$). The mean Bayley PDI score at 18 months was not statistically different among the three groups ($p=0.13$). The mean Behavioral Rating Scale score at 18 months was not statistically different among the three groups ($p=0.30$).	B
LCPUFA-supplemented formula: 15.90% LA, 0.30% AA, 1.40% ALA, 0.01% EPA, 0.32% DHA Control formula: 12.4% LA, 1.1% ALA	There were no significant differences in Bayley MDI and PDI at 18 months or in Knobloch, Passamanick, and Sherrard's test at 9 months between the two formula groups. There were no significant differences in stools to 6 months, crying time (minutes/day) to 6 months, or formula intake to 6 months between the two formula groups. There were no significant differences in the OR of infection-related outcomes or the prescription of antibiotics at 9 months between the two formula groups.	N

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Scott et al., 1998	Randomized Controlled Trial	Infants (n=274) Healthy, full-term Kansas, MO; Portland, OR; Seattle, WA No prematurity, intrauterine growth retardation, congenital anomalies, 5-minute APGAR score <7, or other significant perinatal medical complications	AA/DHA-supplemented formula	Those randomized, formula from first week after delivery Those exclusively breastfeeding, breast milk for first 3 months and then supplementation with Similac + iron Solid food supplementation at 4 months
Willatts et al., 1998a	Randomized Controlled Trial	Infants (n=44) Term UK Mothers from a single maternity hospital	LCPUFA-supplemented formula	Birth to 4 months of age

Amount	Results	Conclusion*
Control formula: No added LCPUFA	There were no significant differences in Bayley scores among the groups for either the Mental Index or the Motor Index.	A
DHA formula group (fish oil): 0.2wt% DHA DHA+AA formula group (egg yolk phospholipid): 0.12wt% DHA, 0.43wt% AA	After controlling for maternal education and site, when comparing all four groups, the vocabulary comprehension score at 14 months was significantly lower in the DHA formula group compared to the breast-feeding group (p=0.017). After controlling for maternal education and site, when comparing only the three formula groups, the vocabulary production score at 14 months was significantly lower in the DHA formula group compared to the control formula group (p=0.027). No other reported associations between MacArthur Communicative Development Inventories at 14 months and the formula groups and those breast-feeding were found to be significant.	
Unsupplemented formula (g/100 g fat): 11.40 LA, 0.70 ALA, <0.10 AA, no DHA LCPUFA-supplemented formula (g/100 g fat): 11.50-12.80 LA, 0.60-0.65 ALA, 0.30-0.40 AA, 0.15-0.25 DHA	The median quartiles for entire problem intention score (p=0.035) and the cover step intention score (p=0.032) were significantly higher in the LCPUFA-supplemented group compared to the unsupplemented group. The median quartiles for entire problem intentional solutions score (p=0.021) and cover step intentional solutions (p=0.005) were significantly higher in the LCPUFA-supplemented group compared to the unsupplemented group. There were no significant differences in the median quartiles for the barrier step or cloth step for either the intention score or the intentional solutions score.	B

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Willatts et al., 1998b	Randomized Controlled Trial	Infants (n=40) Term Birth weight 2500-4000 g Dundee, UK Mean maternal age about 27 years Mean maternal education about 17 years Demonstrated either an early or late peak fixation on the habituation assessment undertaken at 3 months of age	LCPUFA-supplemented formula	Birth to 4 months of age
Carlson and Werkman, 1996	Randomized Controlled Trial	Infants (n=59) Mean gestational age about 28 weeks Birth weight 747-1275 g Predominantly Black Memphis, TN Mean mothers' education about 12 years No need for mechanical ventilation at that time; intraventricular hemorrhage > grade 2; retinopathy of prematurity > stage 2; surgery for necrotizing enterocolitis; weight < the fifth percentile for gestational age; history of maternal substance abuse	DHA-supplemented formula	Preterm formula from 3 days to 2 months of age Term formula from 2 months to 12 months of age

Amount	Results	Conclusion*
Unsupplemented formula (g/100 g fat): 11.40 LA, 0.70 ALA, <0.10 AA, no DHA LCPUFA-supplemented formula (g/100 g fat): 11.50-12.80 LA, 0.60-0.65 ALA, 0.30-0.40 AA, 0.15-0.25 DHA	There were no significant differences in 9-month problem-solving scores (intention score and number of solutions) between the two groups. For those who had an early peak fixation at 3 months, there were no significant differences in 9-month problem-solving score (intention score or intentional solutions) between the two groups (p=0.18). For those who had a late peak fixation at 3 months, the number of intentional solutions was significantly higher in the LCPUFA-supplemented group compared to the unsupplemented group (p <0.02).	B
All in g/100 g total fatty acids Preterm control formula: 21.20 LA, 2.40 ALA, no EPA or DHA Preterm DHA-supplemented formula: 21.20 LA, 2.40 ALA, 0.06 EPA, 0.20 DHA Term formula: 34.30 LA, 4.80 ALA, no EPA or DHA	At 12 months of age, the DHA-supplemented group had statistically more number of looks to familiar (p<0.05) and less seconds of time/novel looks (p<0.05) compared to the controls. No other statistically significant results were reported on visual attention.	B

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Werkman and Carlson, 1996	Randomized Controlled Trial	Infants (n=67) Mean gestational age 29 weeks Birth weight 748-1398 g Can tolerate enteral; intakes >462 kJ/kg body weight/day for 5-7 days Predominantly Black Memphis, TN Mean maternal age 23 years Mean mothers' education about 11.5 years No need for mechanical ventilation at that time; intraventricular hemorrhage > grade 2; retinopathy of prematurity > stage 2; surgery for necrotizing enterocolitis; weight < the fifth percentile for gestational age; history of maternal substance abuse	DHA-supplemented formula	Preterm formula until discharge Term formula from discharge until 9 months past term Other foods gradually added to diet at about 4 months past term Mixed diet, including whole cow's milk from 9 to 12 months
Agostoni et al., 1995	Randomized Controlled Trial	Infants (n=86) Mothers' mean age = about 30 years Gestational age between 37-42 weeks, weight at birth appropriate for gestational age Milan, Italy APGAR score better than 7 at 5 minutes, absence of disease	LCPUFA-supplemented formula	Within 3 days until 4 months of age

Amount	Results	Conclusion*
All in g/100 g total fatty acids Preterm control formula: 19.1 LA, 3.0 ALA, no EPA or DHA Preterm DHA-supplemented formula: 18.7 LA, 3.1 ALA, 0.3 EPA, 0.2 DHA Term control formula: 33.2 LA, 4.8 ALA, no EPA or DHA Term DHA-supplemented formula: 32.6 LA, 4.9 ALA, 0.3 EPA, 0.2 DHA	"Diet did not significantly influence look duration during familiarization, but there was a trend toward shorter look duration in DHA-supplemented infants compared to the controls." At 6.5 months of age, the DHA-supplemented group had a statistically higher number of total looks ($p<0.01$), number of looks to novel ($p<0.01$), and number of looks to familiar ($p<0.05$) compared to the controls. At 9 months of age, the DHA-supplemented group had a statistically higher number of total looks ($p<0.01$), number of looks to novel ($p<0.01$), number of looks to familiar ($p<0.05$), and less seconds for average time/look ($p<0.05$) compared to the controls. At 12 months, the DHA-supplemented group had a statistically shorter novel time as a percentage of total time ($p<0.05$), more seconds of time to familiar ($p<0.05$), and a higher number of total looks ($p<0.01$), number of looks to novel ($p<0.05$), and number of looks to familiar ($p<0.05$) compared to the controls. No other significant results were reported for visual attention.	B
Supplemented formula (g/100 g fat): 10.80 LA, 0.30 GLA, 0.73 ALA, 0.44 AA, 0.05 EPA, 0.30 DHA Standard formula (g/100 g fat): 11.10 LA, 0.70 ALA Human milk (g/100 g fat): 6.9-16.4 LA, 0.1-0.9 GLA, 0.7-1.3 ALA, 0.2-1.2 AA, 0.0-0.6 EPA, 0.1-0.6 DHA	The mean developmental quotient (DQ) at 4 months for those in the standard formula group was statistically lower from the DQ in the supplemented formula group ($p<0.05$) and the breast-feeding group ($p<0.05$). There was no statistical difference between the mean DQ at 4 months of the supplemented formula group and the breast-feeding group.	B

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
McCann and Ames, 2005	Review	Summary of observational, RCTs, other experimental and animal studies	DHA status and LCPUFA-supplemented formula	
Bryan et al., 2004	Review	Summary of the literature (all designs)	PUFA from breast milk or formula	
Jacobson, 1999	Review	Mostly 2 prospective longitudinal studies Detroit study on effects of prenatal exposure to alcohol Michigan study of effects of pre- and postnatal exposure to PCBs	LCPUFA-supplemented formula	

Amount	Results	Conclusion*
	"Evidence from chronic dietary restriction rodent studies . . . shows that the addition of DHA to diets of animals whose brain concentration of DHA have been severely reduced restored control performance levels."	B
	"Formula comparison and maternal supplementation studies in humans and ALA dietary restriction studies in nonhuman primates both link the availability of n-3 LCPUFAs to the development of visual attention" and higher DHA status to enhanced neuromotor development. RCTs in humans have often shown no effect of "LCPUFA supplementation on cognitive or behavioral performance and some reviewers have considered that, overall, the evidence was insufficient to conclude that LCPUFA supplementation benefited development."	
	"There is moderate evidence that PUFAs, and long-chain omega-3 PUFAs in particular, from either breast milk or supplemented infant formula, are beneficial in the development of visual acuity and cognitive performance in infants."	B
	"There is very limited empirical evidence, due to the small number of extant studies, for the beneficial effects of PUFAs, and omega-3 PUFAs in particular, on cognitive performance in older children."	
	"Evidence suggest that omega-3 PUFAs may have a role in the control of the symptoms of neurological disorders such as ADHD and dyslexia."	
	"Any comparisons between breastfed and supplemented groups should include measures of maternal IQ and quality of parenting on which these groups tend to differ."	B
	"Animal and human studies indicating a relation between LCPUFA supplementation and enhanced visual acuity and shorter visual fixations may, in fact, represent relatively independent effects of supplementation on both acuity and cognitive processing speed."	

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Daniels et al., 2004	Cohort	Infants (n=1054) Mothers' mean age = 29 years Majority of mothers with at least an *O* level (moderate) education Bristol, UK Singleton, term births Avon Longitudinal Study of Parents and Children (ALSPAC)	Seafood	Maternal fish intake: 32 weeks of gestation Breast-feeding practices: 15 months after birth Infant fish intake: 6 and 12 months after birth Total mercury concentration: Cord blood at birth
Innis et al., 2001	Cohort	Infants (n=83) Term Birth weight 2500-4500 g Mean mothers' age 32 years British Columbia Intend to breast-feed for 3 months, no solid foods for at least the first 4 months after birth No mothers with substance abuse, communicable diseases, metabolic or physiologic problems, infections likely to influence fetal growth, or multiple births No infants with evidence of metabolic or physical abnormalities	Fatty acids in blood from infants and milk from mothers	2 months of age

Amount	Results	Conclusion*
Maternal fish intake categories (during pregnancy): 1 = Rarely/never 2 = 1 meal/2 weeks 3 = 1-3 meals/week 4 = 4+ meals/week	Children whose mothers ate 1-3 fish meals/week and 4+ fish meals/week had significantly lower odds of low MCDI scores for social activity (OR=0.6, 95% CI 0.5-0.8 and OR=0.7, 95% CI 0.5-0.9, respectively) than the children whose mothers rarely or never ate fish during pregnancy.	B
Child fish intake categories (6 months of age): 1 = Rarely/never 2 = 1+ meal/week	Children whose mothers ate 1-3 fish meals/week and 4+ fish meals/week had significantly lower odds of low DDST scores for language (OR=0.7, 95% CI 0.5-0.9 and OR=0.7, 95% CI 0.5-0.9, respectively) than the children whose mothers rarely or never ate fish during pregnancy.	
Child fish intake categories (12 months of age): 1 = Rarely/never 2 = 1+ meal/week	Children who ate 1+ fish meals/week had significantly lower odds of low MCDI scores for vocabulary comprehension (OR=0.7, 95% CI 0.5-0.8) and social activity (OR=0.7, 95% CI 0.6-0.9) and total DDST score (OR=0.8, 95% CI 0.6-0.9). All other odds ratios presented were nonsignificant.	
Infant DHA: (g/100 g fatty acids) Plasma phospholipids = 2.2-8.0 RBC PE = 6.3-13.0 PC = 1.4-4.6	"The ability to correctly discriminate a retroflex compared with dental phonetic contrast at 9 months of age was positively correlated with the plasma phospholipid DHA ($p<0.02$) and the RBC PE at 2 months of age ($p=0.02$)."	B
Infant AA: (g/100 g fatty acids) Plasma phospholipids = 8.1-15.8 RBC PE = 20.2-27.8 PC = 5.6-9.7	"There were no significant correlations between the infants' AA status and the ability to discriminate the native or nonnative language contrasts." "There were no significant correlations between the infant DHA or AA status at 2 months of age and test scores for novelty preference, or the job search task, with adjustments for covariates included in the model."	
Mother's milk: (g/100 g milk fatty acids) DHA = 0.10-2.50 AA = 0.20-0.81 LA = 6.30-21.50 LNA = 0.50-4.10		

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Kodas et al., 2004	Animal	2 generations of female Wistar rats	ALA-deficient diet	Control group: Control diet at birth to 60 days after birth Deficient group: Deficient diet at birth to 60 days after birth Diet reversed group 1: Control diet at day of birth until 60 days after birth Diet reversed group 2: Deficient diet until day 7 postpartum and then control diet from day 7 to day 60 postpartum Diet reversed group 3: Deficient diet until day 14 postpartum and then control diet from day 14 to day 60 postpartum Diet reversed group 4: Deficient diet until day 21 postpartum and then control diet from day 21 to day 60 postpartum

Amount	Results	Conclusion*
ALA-deficient diet: 6% fat African peanut oil <6 mg ALA/100 g of diet 1200 mg LA/100 g of diet Control diet: 60% peanut oil, 40% rapeseed oil 200 mg ALA/100 g of diet 1200 mg LA/100 g of diet	The fatty acid composition of phosphatidylcholine in the hippocampus of 2-month-old rats was as follows: AA was not significantly different among the different diet groups; DHA was significantly higher in the control group and all diet reversed groups compared to the deficient group ($p < 0.05$); n-6:n-3 was significantly lower in the control group and all diet reversed groups compared to the deficient group ($p < 0.05$). These differences were not significant between the control group and the diet reversed groups. The fatty acid composition of phosphatidylethanolamine in the hippocampus of 2-month-old rats was as follows: AA was significantly lower in the control group and all diet reversed groups compared to the deficient group ($p < 0.05$); DHA was significantly higher in the control group and all diet reversed groups compared to the deficient group ($p < 0.05$); n-6:n-3 was significantly lower in the control group and all diet reversed groups compared to the deficient group ($p < 0.05$). These differences were not significant between the control group and the diet reversed groups. The fatty acid composition of phosphatidylserine in the hippocampus of 2-month-old rats was as follows: AA was not significantly different among the different diet groups; DHA was significantly higher in the control group and all diet reversed groups compared to the deficient group ($p < 0.05$); n-6:n-3 was significantly lower in the control group and all diet reversed groups compared to the deficient group ($p < 0.05$). These differences were not significant between the control group and the diet reversed groups. Basal 5-HT levels were significantly higher in the deficient group compared with the control group ($p < 0.05$); there were no significant differences in basal 5-HT levels between the diet reversed groups 1, 2, and 3 and the control group; there were no significant differences in basal 5-HT levels between the diet reversed group 4 and the control group, deficient group, and all other diet reversed groups.	B

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Levant et al., 2004	Animal	Adult female Long-Evans rats	AA/EPA/DPA/DHA-deficient diet	Control diet: Day 1 of pregnancy until end of study Deficient diet: Day 1 of pregnancy until postnatal day 21. Postnatal day 21, half on deficient diet were changed to remediation diet and half stayed on deficient diet
Chalon et al., 2001	Animal	Male rats 2-3 months old	ALA-deficient diet	2-3 months of age

Amount	Results	Conclusion*
Control diet: 0.35 kg/5 kg diet from soybean oil; no detected AA, EPA, DPA, or DHA	"Rats raised on the deficient diet exhibited a decrease in brain DHA content to 80% of control animals at maturity ($p<0.05$)" and an "increase in DPA content to 575% of control animals at maturity ($p<0.001$)."	A
Deficient diet: 0.35 kg/5 kg diet from sunflower oil; no detected AA, EPA, DPA, or DHA	The remediation diet restored brain DHA and DPA content to levels similar to those on the control diet. Catalepsy score was significantly lower in the deficient diet group compared to the control group ($p<0.05$) and the remediation diet group ($p<0.05$).	
Remediation diet: 0.3275 kg/5 kg diet from sunflower oil and 0.0225 kg/5 kg diet from fish oil AA = 0.1 g/100 g fatty acids EPA = 1.6 g/100 g fatty acids DPA = 0.4 g/100 g fatty acids DHA = 3.5 g/100 g fatty acids	In a test of locomotor activity in a novel environment, the deficient diet group exhibited 187% of the activity of the control diet group during the 2-hour observation ($p<0.05$); results were similar between the deficient diet group and the remediation diet group. In the test of amphetamine-stimulated locomotor activity, the deficient diet group exhibited 144% of the activity of the control group ($p<0.05$).	
ALA-deficient diet: 1200 mg LA/100 g diet, <6 mg ALA/100 g diet African peanut oil Diet balanced in n-6 and n-3 PUFA: 1200 mg LA/100 g diet, 200 mg ALA/100 g African peanut oil and rapeseed oil	"Intake of PUFA constitutes an environmental factor able to act on the central nervous system function." "Chronic dietary deficiency in ALA in rats induces abnormalities in several parameters of the mesocortical and mesolimbic dopaminergic systems." "It is proposed that strong links exist among PUFA status, neurotransmission processes, and behavioral disorders in humans."	B

continued

TABLE B-1g Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
de la Presa, Owens, and Innis, 1999	Animal	Newborn male piglets Birth weight >1 kg <12 hours old	GLA/AA/DHA-supplemented formula	<12 hours old to 18 days of age
Delion et al., 1996	Animal	2 generations of female Wistar rats	ALA-deficient diet	2 weeks before mating (second generation)

*B = Evidence of a benefit; N = Evidence of no association or no clear association; A = Evidence of an adverse effect.

Amount	Results	Conclusion*
4 formula diets (all in g/100 g): Diet 1 (Diet D-): 1.6 LA, 0.1 ALA, no GLA, AA, or DHA Diet 2 (Diet D+): 1.9 LA, 0.1 GLA, 0.4 AA, 0.1 ALA, 0.3 DHA Diet 3 (Diet C-): 15.6 LA, 1.5 ALA, no GLA, AA, or DHA Diet 4 (Diet C+): 16.4 LA, 0.1 GLA, 0.4 AA, 1.6 ALA, 0.3 DHA	There were no significant differences in brain weight, brain protein, DNA, cholesterol or phospholipid concentrations, or CNPase activity among the different diet groups. Piglets fed formulas with AA and DHA had significantly higher frontal cortex dopamine, HVA, norepinephrine, tryptophan and serotonin concentrations than piglets fed formulas without AA and DHA. The concentrations of all frontal cortex monoamines and metabolites in piglets fed Diet 2 formula were not different from those of piglets fed Diets 3 and 4. The inclusion of AA and DHA in Diet 4 had no significant effect on any of the frontal cortex monoamines or metabolites measured, compared to Diet 3.	B
ALA-deficient diet: 6% fat as peanut oil 6 mg ALA/100 g diet 1200 mg LA/100 g diet Control diet: 60% peanut oil, 40% rapeseed oil 200 mg ALA/100 g diet 1200 mg LA/100 g diet	In the control diet group, n-3 (mostly DHA) levels reached a maximum in the stratium and a minimum in the frontal cortex at 12 months of age and remained unchanged during aging in the cerebellum. "In the deficient diet group, DHA content considerably reduced as compared with controls." No specific effects of the deficient diet were found on the proportion of any phospholipid classes. In the control diet group, dopamine levels reached a maximum at 6 months of age, were decreased up to 12 months of age, and then stabilized in the stratium and frontal cortex. However, "the levels were not diet related in the stratium but were dramatically reduced in the frontal cortex of deficient rats and remained unchanged throughout all ages." In the control diet group, 5-HT levels increased between 2 and 6 months of age in the stratium and then stabilized; they did not change in the frontal cortex or cerebellum during aging.	N

TABLE B-1h Studies on Allergies: Effects on Infants Supplemented with Omega-3 Fatty Acids in Formula

Author	Study Type	Subjects	Exposure	Timing of Exposure
Calder, 2001	Review	Summary of animal studies and human trials	Fish-oil supplement	
Field et al., 2001	Review	Summary of animal studies and human trials	AA/DHA-supplemented formula	

Amount	Results	Conclusion*
	"Animal studies have shown that dietary fish oil results in altered lymphocyte function and in suppressed production of proinflammatory cytokines by macrophages."	B
	"Clinical studies have reported that fish-oil supplementation has beneficial effects in rheumatoid arthritis, inflammatory bowel disease, and among some asthmatics."	
	"The effect of fatty acids during pregnancy upon the maternal immune system and upon that of the infant are not known."	
	"Recent research has been directed at the neurological, retinal, and membrane benefits of adding AA and DHA to infant formula. In adults and animals, feeding DHA affects T-cell function. However, the effect of these lipids on the development and function of the infant's immune system is not known."	N
	"The addition of small amounts of DHA and AA (at levels similar to that in human milk) to preterm infant formula can influence the concentration, proportion, maturation, and cytokine production of peripheral blood lymphocytes."	

continued

TABLE B-1h Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Field et al., 2000	Randomized Controlled Trial	Infants (n=44) Preterm, medically stable Edmonton, AB, Canada Appropriate weight for gestational age and receive 100% daily fluid and energy requirements enterally by day 14 postpartum No major congenital infection, significant neonatal morbidity, or acute illness that precluded feeding by mouth; no mixed feedings or corticosteroids, red cell, and plasma transfusions, or intravenous lipid emulsion beyond day 8 postpartum	AA/DHA-supplemented formula	Before day 8 postpartum until day 42 postpartum

*B = Evidence of a benefit; N = Evidence of no association or no clear association.

Amount	Results	Conclusion*
Standard commercial preterm formula group (% weight of total fatty acids): 12.8 LA, 1.4 ALA, no AA or DHA Supplemented preterm formula group (% weight of total fatty acids): 12.10 LA, 1.50 ALA, 0.49 AA, 0.35 DHA	At 14 days postpartum, infants in the supplemented formula group had significantly higher hematocrit (L/L) concentrations compared to those in the human milk group ($p < 0.05$). At 14 days postpartum, infants in the human milk group had significantly higher monocytes compared to both the standard formula group and the supplemented formula group ($p < 0.05$). At 42 days postpartum, infants in the standard formula group had significantly higher T helper phenotypes and CD4/CD8 phenotypes compared to both the supplemented formula group and the human milk group ($p < 0.05$). At 42 days postpartum, infants in the standard formula group had significantly lower monocytes compared to the human milk group ($p < 0.05$). At 42 days postpartum, infants in the human milk group had significantly higher B cells compared to those in both formula groups ($p < 0.05$). At 42 days postpartum, infants in the standard formula group had significantly higher sIL-2R production compared to the supplemented formula group ($p < 0.05$) and significantly lower IL-10 production compared to the human milk group ($p < 0.05$). No other reported results were found to be significant.	B

TABLE B-1i Studies on ADHD: Effects on Children Supplemented with Omega-3 Fatty Acids in Foods Other Than Exclusively Breast Milk or Infant Formula Experimental Studies in Humans

Author	Study Type	Subjects	Exposure	Timing of Exposure
Richardson, 2004	Review	Summary of RCTs	HUFA supplement	
Hirayama et al., 2004*	Randomized Controlled Trial	Children (n=40) Aged 6-12 years Recruited from a summer camp for children with psychiatric disorders Diagnosed or suspected as ADHD	DHA supplement	2 months

Amount	Results	Conclusion**
	Omega-3 fatty acids, particularly EPA, may be beneficial in the management of dyslexia, dyspraxia, and ADHD. There is no evidence that omega-6 fatty acids are beneficial in the management of dyslexia, dyspraxia, and ADHD, but positive results have been found using an omega-3:omega-6 combination for both ADHD and dyslexia.	B
DHA group: Fermented soybean milk 3 times/ week (600 mg DHA/125 mL) Bread rolls 2 times/week (300 mg DHA/45 g) Steamed bread 2 times/week (600 mg DHA/60 g) Total = 3600 mg DHA, 700 mg EPA/week Control group: Placebo food containing olive oil instead of DHA-rich fish oil	Short-term visual memory was significantly improved in the control group from baseline until the end of the study (p=0.02), but not in the DHA group. The short-term visual memory was significantly better in the control group than in the DHA group (p=0.02). The number of errors of omission and commission were significantly improved in the continuous performance test in the control group from baseline until the end of the study (p=0.02 and p=0.01, respectively). The number of errors of commission were significantly higher in the DHA group than in the control group (p=0.001).	A

continued

TABLE B-1i Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Harding et al., 2003*	Trial	Boys and girls (n=20) Aged 7-12 years Diagnosed with ADHD No other medication or treatment, street drugs, other nutritional or botanical supplements, comorbid disorders	Multivitamin, multiple mineral, phytonutrients, essential fatty acid supplements	4 weeks
Stevens et al., 2003*	Randomized Controlled Trial	Boys and girls (n=47) Aged 6-13 Central Indiana = 100-mile radius of West Lafayette Those with diagnosed ADHD and those without ADHD No chronic health problems Presence of 1+ severe symptoms or several mild symptoms	PUFA supplement	4 months

Amount	Results	Conclusion**
Groups determined by parental choice Ritalin group: 5-15 mg Ritalin 2-3 times daily Supplement group: A multivitamin, multimineral, phytonutrients, essential fatty acids (180 mg EPA and 120 mg DHA from salmon oil and 45 mg GLA from borage oil) and phospholipids (soy lecithin), probiotics, and amino acids	Both the Ritalin group and the supplement group showed significant gains in the Full Scale Response Control Quotient and the Full Scale Attention Control Quotient scores ($p \delta 0.01$ and $p \delta 0.001$, respectively). There were no significant differences in improvement between the two groups.	B
PUFA group: 8 capsules of PUFA/day 60 mg DHA, 10 mg EPA, 5 mg AA, 12 mg GLA, 3 mg vitamin E/capsule Placebo group: 8 capsules of placebo/day 0.8 g olive oil/capsule	Based on those who completed the intervention, the change in teacher hit reaction time (measured both in ms and T-score) was significantly greater in the PUFA group than in the placebo group (p=0.05 and p=0.02, respectively) at 4 months. At baseline, there were no significant differences in parents' DBD and teachers' DBD scores between the two groups; after 4 months of treatment the number of children who improved on the parents' DBD attention and oppositional/defiant disorder scales was significantly higher in the PUFA group than in the placebo group (p=0.09 and p=0.02, respectively). No other significant differences were found between the two groups.	B

continued

TABLE B-1i Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Richardson and Puri, 2002*	Randomized Controlled Trial	Boys and girls (n=41) Aged 8-12 years Northern Ireland Referred to a school for children with specific literacy problems No official diagnosis of ADHD or any other psychiatric disorder; use of fatty acid supplements in last 6 months; consumption of oily fish >2 times/week; history of any other neurological or major psychiatric disorder or other significant medical problems; not in treatment for ADHD	HUFA supplement	12 weeks

Amount	Results	Conclusion**
Supplement group: 186 mg EPA/day, 480 mg DHA/day, 96 mg GLA/day, 60 IU vitamin E/day, 864 mg LA/day, 42 mg AA/day, 8 mg thyme oil/day Placebo: Olive oil	At 3 months, the mean psychosomatic ADHD sub-scale, mean Conners' ADHD index score, and mean DSM inattention score were significantly lower in the supplemented group than in the placebo group (p=0.05, p=0.03, p=0.05, respectively). At 12 weeks, the improvements were significantly greater for the supplemented group compared to the placebo group for the cognitive problems (p=0.01), the anxious/shy subscales (p=0.04), and the Conners' index global scale (p=0.02).	B

continued

TABLE B-1i Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Brue et al., 2001	Randomized Controlled Trial	Boys and girls (n=51) Aged 4-12 years Referred by parents, pediatricians, psychologists, psychiatrists, and educators ADHD diagnosed by a physician or psychologist No serious and preexisting medical or psychological condition or taking a stimulant medication other than Ritalin	Essential fatty acid supplement	Two 12-week trials

Amount	Results	Conclusion**
Trial 1: Treatment Group and Ritalin + Treatment Group: 10 mg Ginkgo biloba, 200 mg Melissa officinalis, 30 mg Grapine, 35 mg dimethylamino-ethanol, 100 mg 1-glutamine Placebo Group and Ritalin + Placebo Group: 200 mg Slippery elm supplement Trial 2: Double Treatment Group and Ritalin + Double Treatment Group: 20 mg Ginkgo biloba, 400 mg Melissa officinalis, 60 mg Grapine, 70 mg dimethylamino-ethanol, 200 mg 1-glutamine Double Treatment + EFA Group and Ritalin + Double Treatment + EFA Group: 20 mg Ginkgo biloba, 400 mg Melissa officinalis, 60 mg Grapine, 70 mg dimethylamino-ethanol, 200 mg 1-glutamine, 1000 mg flaxseed	Based on parent and teacher reports from Trial 1, there were no significant differences in inattentiveness or hyperactive-impulsive subscales between any of the treatment groups and their respective controls. Based on parent reports from Trial 2, those in the double treatment + EFA group had a significantly lower hyperactive-impulsive subscale score than the double treatment group (p=0.03). Based on teacher reports from Trial 2, those in the Ritalin + double treatment + EFA group had a significantly higher inattentive subscale score than the Ritalin + double treatment group (p=0.04). Based on teacher reports from Trial 2, those in the double treatment + EFA group had a significantly higher hyperactive-impulsive subscale score than the double treatment group (p=0.04).	N

continued

TABLE B-1i Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Voigt et al., 2001*	Randomized Controlled Trial	Boys and girls (n=63) Aged 6-12 years 100% White in DHA group; 85% White in placebo group Texas No ineffective treatment with stimulant medication; treatment with other psychotropic medications; previous diagnosis of other childhood psychiatric disorders; use of dietary supplements; occurrence of a significant life event within 6 months; history of head injury or seizures; receipt of special education services for mental retardation or a pervasive developmental disorder; premature birth; exposure to tobacco, alcohol, or other drugs in utero; diagnosis of a disorder of lipid metabolism or other chronic medical condition Previous diagnosis of ADHD Being treated successfully with stimulant medication	Algae-derived triglyceride supplement	4 months

Amount	Results	Conclusion**
Algae-derived TG capsule: 345 mg DHA/day	Between baseline and 4 months, TOVA errors of omission significantly increased (p=0.03-0.01) and color trails 1 (p=0.03-0.01) and color trails 2 (p=0.001) significantly decreased for the supplemented group. Between baseline and 4 months, TOVA errors of commission ($p<0.0003$) and color trails 2 ($p<0.0003$) significantly decreased and TOVA total response time (p=0.03-0.01) significantly increased for the placebo group. "There were no differences between groups at any time on any behavior measure by the parental Conners' Rating Scales."	N

continued

TABLE B-1i Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Stevens et al., 1995*	Case-control	Cases = boys with ADHD (n=53) Control = healthy boys (n=43) Aged 6-12 years North central Indiana Primarily White	Plasma fatty acid analysis	At time of visit
Mitchell et al., 1987*	Case-control	Cases = hyperactive children (n=48) Controls = from two local primary schools (n=49) Boys and girls Mean age about 9 years 92% European About 95% mothers in top three socioeconomic groups Auckland, New Zealand	Serum fatty acid levels	At time of visit
Mitchell et al., 1983*	Case-control	Cases = from a residential school for "maladjusted" children (n=23) Controls = from a normal intermediate school (n=20) Boys and girls Aged 10-13 years for controls Aged 7.5-13 years for cases Auckland, New Zealand	Level of red blood cell essential fatty acids	At time of visit

*Included in Schachter HM, Kourad K, Merali Z, Lumb A, Tran K, Miguelez M. 2005. *Effects of Omega-↑ Fatty Acids on Mental ↑ealth. Summary, E↑idence Report/Tech nology Assessment No. ↑↑↑ (Prepared by the Uni↑ersity of Ottawa E↑idence-based Practice Center under Contract No. ↑↑0-0↑-00↑↑).* Rockville, MD: Agency for Healthcare Research and Quality.

**B = Evidence of a benefit; A = Evidence of an adverse effect; N = Evidence of no association or no clear association.

Amount	Results	Conclusion**
Omega-3 fatty acids as continuous variables	Boys with ADHD had significantly lower mean levels of plasma AA, EPA, and DHA than the controls ($p<0.02$, $p<0.02$, $p<0.03$, respectively). Boys with ADHD had significantly lower mean levels of red blood cell AA ($p<0.02$), 22:4n-6 ($p<0.03$), and DHA ($p<0.06$), and significantly higher mean levels of red blood cell 22:5n-6 ($p<0.05$) compared to the controls.	B
Omega-3 fatty acids as continuous variables	The mean level of DHA from nonfasting blood samples was significantly lower in the hyperactive children than in the controls ($p=0.045$). The mean levels of DGLA and AA from nonfasting blood samples were significantly lower in the hyperactive children than in the controls ($p=0.007$ and $p=0.027$, respectively). No significant differences in blood serum n-3 or n-6 fatty acids were found.	B
Omega-3 fatty acids as continuous variables	The mean levels of LA, DGLA, and AA from fasting blood samples were lower in the "maladjusted" children than in the normal children ($0.05<p<0.01$), although the differences were not significant. The mean level of 22:5n-6 from fasting blood samples was higher in the "maladjusted" children than in the normal children ($0.05<p<0.1$), although this difference was not significant. No other significant differences were found between the two groups in terms of fatty acid levels in fasting blood samples.	N

TABLE B-1j Studies on Allergies and Asthma: Effects on Children Supplemented with Omega-3 Fatty Acids in Foods Other Than Exclusively Breast Milk or Infant Formula

Author	Study Type	Subjects	Exposure	Timing of Exposure
Peat et al., 2004	Randomized Controlled Trial	Pregnant women (n=616) Mean age about 29 years About 47% tertiary educated Sydney, Australia At least one parent or sibling with current asthma or frequent wheeze; fluency in English; a telephone at home; residence within 30 km of the recruitment center No pet at home; vegetarian diet; multiple births; or less than 36 weeks gestation The Childhood Asthma Prevention Study (CAPS)	Tuna-fish oil supplement	Child's age of 6 months to 3 years
Hodge et al., 1998*	Randomized Controlled Trial	Boys and girls (n=39) Aged 8-12 years Sydney, Australia Asthmatic with a history of episodic wheeze in the last 12 months and airway hyperresponsiveness to histamine No other significant diseases; taking regular oral corticosteroids or with known aspirin or dietary salicylate sensitivity	EPA/DHA supplement	6 months

Amount	Results	Conclusion**
Intervention group: 500 mg/day tuna fish oil 184 mg omega-3 fatty acids Placebo group: Sunola oil 83% monounsaturated oil	At 3 years of age, there were no significant differences in prevalence of asthma, wheezing, eczema, and atopy between the intervention group and the placebo group. However, those in the intervention group had significantly lower prevalence of mild or moderate coughing (p=0.03) and atopic coughing (p=0.003) than the placebo group.	N
Omega-3 group: 0.18 g EPA and 0.12 g DHA/capsule 4 capsules/day = 1.2 g omega-3/day Omega-6 group: 0.45 g safflower oil, 0.45 g palm oil, 0.10 g olive oil/capsule No EPA or DHA	"There was no significant change in spirometric function, dose response ratio to histamine or asthma severity score at either 3 or 6 months in either group." "There were no significant differences between groups in TNF± production over time (p=0.22)." "Dietary enrichment of omega-3 fatty acids over 6 months increased plasma levels of these fatty acids, reduced stimulated tumour necrosis factor ± production, but had no effect on the clinical severity of asthma in these children."	N

continued

TABLE B-1j Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Denny et al., 2003	Review	18 cross-sectional studies 4 case-control studies 3 cohort studies	Dietary PUFA	
Smit et al., 1999	Review	All epidemiological evidence	Seafood	

Amount	Results	Conclusion**
	"Very few studies investigated the effects of polyunsaturated fatty acids (PUFAs) on chronic obstructive pulmonary disease (COPD) and asthma, and the results of those that were found showed conflicting results."	N
	"It is very difficult to draw any conclusions on the true impact of dietary PUFA intake on respiratory health."	
	"The evidence in this review suggests that diet does play a role in asthma and COPD, but the causality of association cannot be confirmed because of the observational nature of most of the studies."	
	"The findings of several large studies in adults suggest that high fish intake has beneficial effects on lung function."	B
	"The relationship between fish intake and respiratory symptoms and clinical disease is less evident."	

continued

TABLE B-1j Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Peat et al., 1998*	Review	Longitudinal cohort studies and cross-sectional studies	Diet	

Amount	Results	Conclusion**
	In cross-sectional studies, the risk factors for pres - ence in: 1. Airway narrowing are atopy, family history of asthma, gender (male), and parental smoking; 2. Airway size are low birth weight, parental smoking, and diet (low magnesium or antioxidant intake); 3. Airway hyperresponsiveness are atopy, family history of asthma, high allergen exposure, and diet (high sodium/magnesium or low omega-3 fatty acid intake). In longitudinal studies, the risk factors for ongoing conditions from: 1. Airway narrowing are atopy early in childhood, gender (female), parental smoking, symptoms that begin before age 5, persistent wheeze in childhood in the absence of respiratory infection, and reduced expiratory flow rate; 2. Airway size are atopy, gender (female), and airway hyperresponsiveness; 3. Airway hyperresponsiveness are atopy in early childhood, airway hyperresponsiveness in child - hood, reduced expiratory flow rate, and gender (female). Important future longitudinal studies will be those that divide the broad spectrum of asthma into phenotypic groups.	B

continued

TABLE B-1j Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Takemura et al., 2002*	Case-control	Cases = currently asthmatic students (n=1673) Controls = students who were never asthmatic (n=22,109) Boys and girls Elementary and junior high school students Aged 6-15 years, Tokorozawa City, Japan Tokorozawa Childhood Asthma and Pollinosis Study	Seafood	

Amount	Results	Conclusion**
Fish intake categories: 1 = Almost none 2 = 1-2 times/month 3 = 1-2 times/week 4 = ε3-4 times/week Serving size unspecified; cited that "most of the variation is explained by frequency of use rather than differences in serving sizes"	After adjusting for age, gender, parental history of asthma: The OR for current asthma was slightly significantly higher for those who ate fish 1-2 times/week compared to those who ate fish 1-2 times/month (OR=1.133, 95% CI 1.021-1.258); and Although the ORs for current asthma were not significant for those who ate fish almost never (OR=0.957, 95% CI 0.725-1.263) and ε3-4 times/week (OR=1.334, 95% CI 0.907-1.963) compared to those who ate fish 1-2 times/month, there was a significant positive trend with an increase of fish consumption (p for trend = 0.0078). After adjusting for age, gender, parental history of asthma, and vegetable and fruit intake: The OR for current asthma was slightly significantly higher for those who ate fish 1-2 times/week compared to those who ate fish 1-2 times/month (OR=1.117, 95% CI 1.005-1.241); and Although the ORs for current asthma were not significant for those who ate fish almost never (OR=1.039, 95% CI 0.785-1.376) and ε3-4 times/week (OR=1.319, 95% CI 0.896-1.943) compared to those who ate fish 1-2 times/month, there was a significant positive trend with an increase of fish consumption (p for trend = 0.0349).	A

continued

TABLE B-1j Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Hodge et al., 1996*	Case-control	Boys and girls (n=468) Aged 8-11 Sydney, Australia With airway hyperresponsiveness, wheeze in the last 12 months, and 3-in-5 sample of children with no airway hyperresponsiveness or wheeze in the last 12 months	Seafood	In the past year
Ellwood et al., 2001	Ecological	Children Aged 6-7 and 13-14 years 53 countries The International Study of Asthma and Allergies in Childhood (ISAAC) Data from FAO Food Balance Sheet	PUFA and seafood intake	

Amount	Results	Conclusion**
Total fish intake/week Ever eat fresh fish, fresh oily fish, or fresh non-oily fish	There were no significant differences in total fish intake between children with normal airways (1.2 servings, 95% CI 1.0-1.3), airway hyperresponsiveness (1.2 servings, 95% CI 0.9-1.5), wheeze (1.2 servings, 95% CI 0.8-1.5) and current asthma (1.0 servings, 95% CI 0.8-1.2). Significantly fewer children with asthma ever ate oil fish compared to children with normal airways ($p<0.05$); however, there was no significant difference between those with current asthma and normal children who ate exclusively oily fish. After adjusting for atopy, parental asthma, parental smoking, ethnicity, country of birth, early respiratory illness, and sex: Children who ate oily fish had a significantly lower OR of current asthma when compared to children who did not eat oily fish (OR=0.26, 95% CI 0.09-0.72); and There were no other significant associations found between type of fish (fresh fish, oily fish, non-oily fish) and airway hyperresponsiveness, wheeze, or current asthma.	B
Percentage of total energy consumed as PUFA: 3%-12% Range of fish intake not reported	There were no significant associations found between total PUFA intake (% of total fat) for current wheezing, severe wheezing, allergic rhinoconjunctivitis, and atopic eczema. There was a significant inverse association found between all fish (fresh and frozen) consumption and asthma, allergic rhinoconjunctivitis, and atopic eczema, for the 13- to 14-year-old age group; the same inverse association remained for the 6- to 7-year-old age group, but the association was weaker.	B

continued

TABLE B-1j Continued

Author	Study Type	Subjects	Exposure	Timing of Exposure
Satomi et al., 1994*	Ecological	Boys and girls (n=7742) Aged 6-11 years Japan 1st-, 3rd-, 5th-grade students Coastal schools = fish harvest and consumption are high Inland schools = located far from sea but close to the coast school district	Seafood	

*Included in Schachter HM, Reisman J, Tran K, Dales B, Kourad K, Barnes D, Sampson M, Morrison A, Gaboury I, Blackman J. 2004. *healt h Effects of Omega-ƚ Fatty Acids on Ast h ma. Summary, E ƚidence Report/Tech nology Assessment No. ƚƚ (Prepared by t he Uni ƚersity of Ottawa E ƚidence-based Practice Center under Contract No.ƚƚ0-0ƚ-00ƚƚ). A hRQ Publication No. 0ƚ-E0ƚƚ-ƚ.* Rockville, MD: Agency for Healthcare Research and Quality.

**N = Evidence of no association or no clear association; B = Evidence of a benefit; A = Evidence of an adverse effect.

Amount	Results	Conclusion**
Fish consumption categories: Very often = ε4-5 times/week Relatively often = 2-3 times/week Often = 1 time/week Infrequently = 1-2 times/month Seldom = <1 time/month	Coastal school children who ate reddish fish (sar - dine, mackerel, pike) very often had a significantly lower prevalence of history of asthma than those who seldom ate reddish fish ($p<0.01$). There were no other significant differences for these children based on consumption of pale fish, shellfish, fish-paste, seaweed, and dried fish. Inland school children who ate pale fish (flatfish, sea bream, turbot) and seaweed very often had significantly higher prevalence of history of asthma than those who seldom ate pale fish and seaweed ($p<0.01$; $0.01<p<0.05$, respectively). There were no other significant differences for these children based on reddish fish, shellfish, fish-paste, and dried fish.	B

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Studies on Adult Chronic Diseases

TABLE B-2a Secondary Prevention Studies with Cardiovascular Outcomes

Author	Study Type	Subjects	Exposure
Hooper et al., 2006	Meta-analysis	48 randomized controlled trials 41 cohorts Omega-3 intake for ε6 months in adults Primary and secondary prevention	n-3 supplement

Amount	Results	Conclusion**
High omega-3 fat vs. low omega-3 fat/control Intake differed by 0.1-0.6 g omega-3/day among the two groups (absolute levels not specified)	Based on RCTs, no significant differences were found between the high omega-3 fat group and the low omega-3 fat/control group with regards to risk of mortality (n=15 RCTs; RR=0.87, 95% CI 0.73-1.03), cardiovascu - lar events (n=18 RCTs; RR=0.95, 95% CI 0.82-1.12), cancer or death from cancer (n=10 RCTs; RR=1.07, 95% CI 0.88-1.30), or stroke (n=9 RCTs; RR=1.17, 95% CI 0.91-1.51). Based on cohorts, no significant differences were found between the high omega-3 fat group and the low omega-3 fat/control group with regards to risk of cardiovascular events (n=7 cohorts; RR=0.91, 95% CI 0.73-1.13), cancer or death from cancer (n=7 cohorts; RR=1.02, 95% CI 0.87-1.19), or stroke (n=4 cohorts; RR=0.87, 95% CI 0.72-1.04). Based on three cohorts, those in the low omega-3 fat/control group had a significantly higher risk of mortality compared to those in the high omega-3 fat group (RR=0.65, 95% CI 0.48-0.88).	N

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Hooper et al., 2005	Cochrane Review	48 randomized controlled trials 41 cohorts Primary and secondary prevention	n-3 supplement or advice

Amount	Results	Conclusion**
	Based on RCTs, no significant differences were found between those randomized to n-3 supplementation or advice and those not randomized to n-3 supplementation or advice with regards to total mortality (n=44 RCTs; RR=0.87, 95% CI 0.73-1.03), combined cardiovascular events (n=31 RCTs; RR=0.95, 95% CI 0.82-1.12), cancers (n=10 RCTs; RR=1.07, 95% CI 0.88-1.30), cardiovascular deaths (n=44 RCTs; RR=0.85, 95% CI 0.68-1.06), fatal myocardial infarction (n=38 RCTs; RR=0.86, 95% CI 0.60-1.25), non-fatal myocardial infarction (n=26 RCTs; RR=1.03, 95% CI 0.70-1.50), sudden death (n=37 RCTs; RR=0.85, 95% CI 0.49-1.48), angina (n=25 RCTs; RR=0.78, 95% CI 0.59-1.02), stroke (n=26 RCTs; RR=1.17, 95% CI 0.91-1.51), heart failure (n=20 RCTs; RR=0.51, 95% CI 0.31-0.85), peripheral vascular events (n=17 RCTs; RR=0.26, 95% CI 0.07-1.06), and re-vascularization (n=23 RCTs; RR=1.05, 95% CI 0.97-1.12).	N
	Based on cohort studies, no significant differences were found between those randomized to n-3 supplementation or advice and those not randomized to n-3 supplementation or advice with regards to combined cardiovascular events (n=7 cohorts; RR=0.91, 95% CI 0.73-1.13), cancers (n=10 cohorts; RR=1.02, 95% CI 0.87-1.19), nonfatal myocardial infarction (n=4 cohorts; RR=0.93, 95% CI 0.69-1.26), stroke (n=4 cohorts; RR=0.87, 95% CI 0.72-1.04), peripheral vascular events (n=1 cohort; RR=0.94, 95% CI 0.84-1.04), and revascularization (n=2 cohorts; RR=1.07, 95% CI 0.76-1.50).	
	Based on cohort studies, significant differences were found between those randomized to n-3 supplementation or advice and those not randomized to n-3 supplementation or advice with regards to total mortality (n=3 cohorts; RR=0.65, 95% CI 0.48-0.88), cardiovascular deaths (n=11 cohorts; RR=0.79, 95% CI 0.63-0.99), fatal myocardial infarction (n=2 cohorts; RR=0.42, 95% CI 0.21-0.82), and sudden death (n=1 cohort; RR=0.44, 95% CI 0.21-0.91).	

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Konig et al., 2005	Meta-analysis	7 observational studies (primary prevention) 4 RCTs (secondary prevention)	Seafood
Burr et al., 2005	Review	Review of two randomized controlled trials (Burr et al., 1989, 2003 below) Secondary prevention	Dietary advice
Harper and Jacobson, 2005	Review	Systematic literature review of 14 randomized controlled trials Northern Europe, Southern Europe, India Excluded if trial involved >1 intervention unless in a prospective 2 · 2 design Patients followed for ε1 year Secondary prevention	6 on fish oil 2 on fish 5 on ALA suppl. 2 on ALA-enriched diets

Amount	Results	Conclusion**
Servings/week, a continuous number 1 serving = 100 g	Among those with no preexisting CHD (from observational studies), the linear regression model showed that each one serving increase in fish consumption per week reduces one's risk of CHD death by 0.039 (95% CI −0.066 to −0.011) but does not significantly change one's risk of nonfatal MI by (ΔRR=0.0083, 95% CI −0.012 to 0.028). "The information available is insufficient for the purposes of quantitatively analyzing the impact of fish consumption on CHD risk for individuals with preexisting CHD" (from RCTs).	B
See Burr et al., 1989, 2003 below	"It appeared that fish oil, which protected post-MI male patients in DART, increased the risk of cardiac death in men with angina, being particularly associated with sudden death." "The apparently conflicting findings may be attributable to the different clinical conditions of the subjects . . . together with different effects of dietary fish and fish oil."	N
	"The evidence supports a role for fish oil (EPA or DHA) or fish in secondary prevention, because the clinical trials have demonstrated a reduction in total mortality, CHD death, and sudden death." "Evidence from these trials had indicated that EPA plus DHA supplementation in the range of 0.5-1.8 g/day provides significant benefit." "The data on the plant-based n-3 PUFA, ALA, is very promising. However, the existing studies were small, and a large randomized controlled trial is needed before recommendations can be definitely made for CHD prevention." "The data for ALA show possible reductions in sudden death and nonfatal myocardial infarction, suggesting other potential cardioprotective mechanisms other than a predominately antiarrhythmic role."	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Leaf et al., 2005	Randomized Controlled Trial	Men and women (n=402) Mean age about 65 years 18 US centers Had a cardioverter defibrillator implanted because of a history of cardiac arrest, sustained ventricular tachycardia, or syncope with inductive, sustained ventricular tachycardia or ventricular fibrillation during electrophysiologic studies Follow-up of 12 months Secondary prevention	n-3 supplement

Amount	Results	Conclusion**
Treatment: Four 1 g gelatin capsules of an ethyl ester concentrate of n-3 fatty acids (2.6 g EPA+DHA) Placebo: Four 1 g capsules of olive oil	After controlling for sex, left ventricular ejection fraction (continuous), New York Heart Association class III congestive heart failure, history of myocardial infarction, history of prior defibrillator therapies for ventricular tachycardia or ventricular fibrillation, time from implanted cardioverter/defibrillator implant (continuous), and sustained ventricular tachycardia as the indication for the implanted cardioverter defibrillator: The intent-to-treat analysis provided a significant relative risk of time to first event of 0.67 (95% CI 0.47-0.95, p=0.024) for all confirmed events among those in the treatment group compared to the placebo group; The on-treatment analysis (for all who had taken any of their prescribed supplements) provided a significant relative risk of time to first event of 0.67 (95% CI 0.46-0.98, p=0.037) for all confirmed events among those in the treatment group compared to the placebo group; and The on-treatment analysis (for all on-treatment at least 11 months) provided a significant relative risk of time to first event of 0.52 (95% CI 0.32-0.83, p=0.0060) for all confirmed events among those in the treatment group compared to the placebo group. Similar results were found when probable events were also included.	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Raitt et al., 2005	Randomized Controlled Trial	Men and women (n=200) Mean age about 62 Patients at six medical centers in the United States Receiving an implantable cardioverter defibrillator for an electrocardiogram-documented episode of sustained ventricular tachycardia or ventricular fibrillation that was not the result of acute myocardial infarction or a revisible cause or who had a preexisting implantable cardioverter defibrillator and had received implantable cardioverter/defibrillator therapy for an electrocardiogram-documented episode of sustained ventricular tachycardia or ventricular fibrillation within the last 3 months No class I or class II antiarrhythmic medications; ε1 fatty fish meal/week; flaxseed oil, cod-liver oil, or fish-oil supplements in the last month Follow-up of 2 years Secondary prevention	n-3 supplement

Amount	Results	Conclusion**
Treatment: 1.8 g/day fish oil (42% EPA and 30% DHA) Placebo: Olive oil (73% oleic acid, 12% palmitic acid, 0% EPA+DHA)	There was a significant difference in the number of patients hospitalized for neurological conditions among those assigned to the placebo compared to those assigned to the treatment (p=0.04). However, there were no other significant differences found in mortality, hospitalizations, coronary revascularization, myocardial infarction, cancer, and diarrhea between the two groups. There were no significant differences in the time to first episode of implantable cardioverter/defibrillator therapy for ventricular tachycardia or ventricular fibrillation after randomization between the two groups (p=0.19). However, among those with qualified arrhythmia at the time of study entry, those assigned to fish oil had significantly greater incidence of ventricular tachycardia or ventricular fibrillation treated by the implantable cardioverter defibrillator compared to those assigned to placebo (p=0.007).	A

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Baer et al., 2004	Randomized Crossover Trial	Men (n=50) Aged 25-60 years All races Beltsville, MD In good health, with no hypertension, hyperlipidemia, diabetes, peripheral vascular disease, gout, liver or kidney disease, or endocrine disorders Fasting plasma HDL-c >0.65 mmol/L, triacylglycerol <3.39 mmol/L, and 85-120% of their sex-specific ideal BMI No lipid-lowering drugs, blood pressure medication, or dietary supplements, or eating habits inconsistent with the study protocol 30-week intervention (six diets for 5 weeks each) Primary prevention	Diet

Amount	Results	Conclusion**
Diets 1-5: 38.9% energy from fat, 15% energy from protein, 46.1% energy from digestible carbohydrates Diet 6: 30.4% energy from fat, 54.6% energy from carbohydrate Diet 1 (carbohydrate diet): 8.5% of energy from fat replaced by digestible carbohydrate Diet 2 (oleic acid diet): 8% of energy enriched with oleic acid Diet 3 (LMP diet): 8% of energy enriched with lauric (L), myristic (M), and palmitic (P) acids Diet 4 (stearic acid diet): 8% of energy enriched with stearic acid Diet 5 (trans fatty acid diet): 8% of energy enriched with trans fatty acids Diet 6 (trans fatty acid + stearic acid diet): 4% energy enriched with trans fatty acids and 4% of energy enriched with stearic acid	After 5 weeks on the stearic acid diet, the least squares mean plasma fibrinogen levels were significantly higher than after 5 weeks on all other diets ($p<0.05$). After 5 weeks on the trans fatty acid diet, the least squares mean plasma C-reactive protein levels were significantly higher than after 5 weeks on all other diets ($p<0.05$). After 5 weeks on the oleic acid diet, the least squares mean plasma interleukin 6 levels were significantly lower than after 5 weeks on all other diets, except for the trans fatty acid + stearic acid diet ($p<0.05$). After 5 weeks on the trans fatty acids diet, the least squares mean plasma C-reactive protein levels were significantly higher than after 5 weeks on the carbohydrate diet, the oleic diet, and the trans fatty acid + stearic acid diet ($p<0.05$). After 5 weeks on the oleic acid diet, the least squares mean plasma interleukin 6 levels were significantly lower than after 5 weeks on the trans fatty acid diet, stearic acid diet, or the LMP diet ($p<0.05$). After 5 weeks on the oleic acid diet, the least squares mean plasma E-selectin levels were significantly lower than after 5 weeks on all other diets, except for the carbohydrate diet ($p<0.05$). After 5 weeks on the trans fatty acids diet, the least squares mean plasma E-selectin levels were significantly higher than after 5 weeks on all other diets ($p<0.05$). There were no other significant differences reported between the diets with regards to fibrinogen, C-reactive protein, interleukin 6, or E-selectin levels.	N

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Burr et al., 2003	Randomized Controlled Trial	Men (n=3114) Aged <70 years South Wales, UK Being treated with angina Mortality ascertained at 3-9 years after enrollment No exertional chest pain or discomfort; men awaiting coronary artery by-pass surgery, men who already ate oily fish twice a week, men who could not tolerate oily fish or fish oil, men who appeared to be unsuitable on other grounds (e.g., other serious illness, likelihood of moving out of area) The Diet and Angina Randomized Trial (DART 2) Follow-up of 3 years (after last subject was recruited) Secondary prevention	Dietary advice

Amount	Results	Conclusion**
Fish advice = eat at least 2 portions of oily fish each week or take up to 3 g of fish oil as a partial or total substitute	Those given fish advice had significantly higher percentage of cardiac deaths (p=0.02) and sudden deaths (p=0.02) compared to those who did not receive fish advice. There was not a significant difference in the number of total deaths between these two groups.	A
Fruit/vegetable advice = eat 4-5 portions of fruit and vegetables and drink at least 1 glass of natural orange juice daily, and also increase the intake of oats	No significant differences were found between the fruit/vegetable advice group and the no fruit/vegetable advice group for total number of deaths, number of cardiac deaths, or num - ber of sudden deaths.	
Both = a combination of both of these forms of advice	After adjusting for age, smoking, previous MI, history of high blood pressure, diabetes, BMI, serum cholesterol, medication, and fruit advice or fish advice:	
Sensible eating = non - specific advice that did not include either form of advice	Those who received fish advice had a slightly significant higher hazard ratio for cardiac deaths (HR=1.26, p=0.047) and a sig - nificant higher hazard ratio for sudden death (HR=1.54, p=0.025), compared to those who did not receive fish advice.	
	There were no significant associations found between those who received fruit/vegetable advice vs. those who did not and all deaths, cardiac deaths, or sudden deaths.	

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Marchioli et al., 2002	Randomized Controlled Trial	Men and women (n=11,323) No age limits Gruppo Italiano per lo Studio della So - pravivivenza nell'Infarto miocardico-Prevenzione (GISSI trial) Recent MI Follow-up of 3.5 years (about 38,418 person-years) Secondary prevention	n-3 supplement

Amount	Results	Conclusion**
n-3 fatty acids group = 1 g/day Vitamin E group = 300 mg/day Combination group Control group	After adjusting for age, sex, complications after myocardial infarction, smoking habits, history of diabetes mellitus and arterial hypertension, total blood cholesterol, HDL cholesterol, fibrinogen, leukocyte count, and claudication intermittens: Those who received n-3 fatty acids had a significantly lower relative risk of death, nonfatal MI, and nonfatal stroke at 9 months, 12 months, and 42 months of follow-up than the controls (RR=0.76, 95% CI 0.60-0.97 at 9 months, RR=0.79, 95% CI 0.63-0.98 at 12 months, and RR=0.85, 95% CI 0.74-0.98 at 42 months). The relative risks at 3 and 6 months of follow-up were also lower in the n-3 fatty acid group compared to the controls, but they were not significant. Those who received n-3 fatty acids had a significantly lower relative risk of CVD death, nonfatal MI, and nonfatal stroke at 9 months (RR=0.75, 95% CI 0.58-0.97), 12 months (RR=0.78, 95% CI 0.62-0.99), and 42 months (RR=0.80, 95% CI 0.68-0.94) of follow-up than the controls. The relative risks at 3 and 6 months of follow-up were also lower in the n-3 fatty acid group compared to the controls, but they were not significant.	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Ness et al., 2002	Randomized Controlled Trial	Men (n=2033) Aged <70 years 21 hospitals in south Wales and south-west England Survived an MI Diet and Reinfarction Trial (DART) 21,147 person-years of follow-up Secondary prevention	Dietary advice

Amount	Results	Conclusion**
Fish advice = eat at least 2 portions of fatty fish each week and as much other fish as they could manage (using fish oil capsule as a partial or total replacement if necessary) Fat advice = aimed at reducing total fat and increasing the polyunsaturated to saturated fat ratio Fiber advice = eat at least 6 slices of wholemeal bread per day or an equivalent amount of cereal fiber	After adjusting for myocardial infarction, angina, hypertension at baseline; x-ray evidence of cardiomegaly, pulmonary congestion or pulmonary edema at baseline; and treatment with "-blockers, other anti-hypertensives, digoxin/antiarrhythmics, or anticoagulants: Those who received fish advice had a significantly lower hazard ratio for all-cause mortality at 0-2 years of follow-up (HR=0.73, 95% CI 0.56-0.95) and a significantly higher hazard ratio at 2-5 years of follow-up (HR=1.31, 95% CI 1.01-1.71) compared to those who did not receive fish advice. However, there were no significant differences between the two groups and all-cause mortality after 5 years of follow-up; Those who received fish advice had a significantly lower hazard ratio for coronary heart disease at 0-2 years of follow-up (HR=0.68, 95% CI 0.51-0.91) compared to those who did not receive fish advice. After 2 years of follow-up, there were no significant differences between the two groups and their risk of coronary heart disease; and There were no significant differences between those who received fish advice vs. those who did not and risk of stroke throughout 10 years of follow-up.	N

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Nilsen et al., 2001	Randomized Controlled Trial	Men and women (n=300) Aged >18 years Central Hospital in Rogaland, Stavanger, Norway Suffered from acute MI Discontinued regular supplementation of other fish oil products No assumed noncompliance; expected survival <2 years because of severe heart failure; ongoing gastrointestinal bleeding or verified stomach ulcer; thrombocytopenia or blood platelets <100 · 109/L; liver insufficiency; participation in any other study; residence outside the recruitment area Mean follow-up time of 1.5 years Secondary prevention	n-3 supplement
GISSI Investigators, 1999*	Randomized Controlled Trial	Men and women (n=11,324) No age limits Recent MI (δ3 months) No contraindications to the dietary supplements; were able to provide informed written consent, had no unfavorable short-term outlook (e.g., overt congestive heart failure, cancer, etc.) 42 months of follow-up Gruppo Italiano per lo Studio della So - pravivivenza nell'Infarto miocardico-Prevenzione (GISSI trial) Secondary prevention	n-3 supplement

Amount	Results	Conclusion**
Fish oil = 850-880 mg EPA+DHA/capsule Control = same amount in corn oil 2 capsules twice a day	When compared to the corn oil group, there were no significant associations found between fish oil and fatal cardiac events and resuscitations, nonfatal cardiac events, revascularization, total mortality, time to first event, or cardiac event or revascularization.	N
n-3 PUFA alone vs. vitamin E alone vs. combination of the two vs. no supplement (control) Absolute amounts not specified	In the four-way analysis, those who received n-3 PUFA had a significantly lower relative risk of death, nonfatal MI, and nonfatal stroke (RR=0.85, 95% CI 0.74-0.98) and cardiovascular death, nonfatal MI, and nonfatal stroke (RR=0.80, 95% CI 0.68-0.95) compared to the controls. In the four-way analysis, those who received n-3 PUFA had a significantly lower relative risk of all fatal events (RR=0.80, 95% CI 0.67-0.94), all cardiovascular deaths (RR=0.70, 95% CI 0.56-0.87), cardiac death (RR=0.65, 95% CI 0.51-0.82), coronary death (RR=0.65, 95% CI 0.51-0.84), and sudden death (RR=0.55, 95% CI 0.40-0.76). Similar results were also found in the two-way analysis.	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Singh et al., 1997	Randomized Controlled Trial	Men and women (n=360) Mean age of 48.5 years Admitted to the Medical Hospital and Research Center, Moradabad Clinical diagnosis of acute MI in the preceding 24 hours Indian Experiment of Infarct Survival (IEIS-4) Secondary prevention	n-3 supplement
Burr et al., 1989	Randomized Controlled Trial	Men (n=2033) Aged <70 years South Wales, UK From those admitted to 21 hospitals for acute MI No diabetes, those awaiting cardiac surgery, or those who already intended to eat one of the intervention diets 2 years of follow-up The Diet and Reinfarction Trial (DART) Follow-up of 2 years Secondary prevention	Dietary advice

Amount	Results	Conclusion**
Fish oil = 1.08 g/day EPA + 0.72 g/day DHA Mustard oil = 2.9 g/day ALA Placebo = 100 mg/day aluminum hydroxide	Compared to the placebo group, those in the fish oil group had significantly lower relative risks of angina pectoris (RR=0.42, 95% CI 0.22-0.77), total arrhythmias (RR=0.46, 95% CI 0.21-0.98), total cases with poor left ventricular function (RR=0.48, 95% CI 0.28-0.82), NYHA class III and IV heart failure (RR=0.44, 95% CI 0.18-0.88), and total cardiac events (RR=0.70, 95% CI 0.29-0.90). Compared to the placebo group, the fish oil group also had lower relative risks of ventricular ectopic beats (>8/minute and >3 consecutively), left ventricular enlargement, hypotension, sudden cardiac death, total cardiac death, and nonfatal reinfarction, but these were not significant. Serious concerns have been raised about the performance and conclusions of this trial and other related publications by this investigator.	B
Fat advice = reduce fat to 30% of total energy and increase polyunsaturated to saturated ratio to 1.0	Total mortality and IHD mortality was significantly lower in the fish advice group than in the non-fish advice group ($p<0.05$ and $p<0.01$, respectively).	B
Fish advice = consume at least 2 weekly portions of 200-400 g fatty fish (or 0.15 g of MaxEPA capsules daily if one could not tolerate fish) Fiber advice = increase intake of cereal fiber to 18 g daily	There were no significant differences in nonfatal MI or IHD events in the fish advice group and the non-fish advice group. There were no significant differences in total mortality, IHD deaths, nonfatal MI, or IHD events between the fat advice group and the non-fat advice group or between the fiber advice group and the non-fiber advice group. After controlling for history of MI, angina, or hypertension; X-ray evidence of cardiomegaly, pulmonary congestion, or pulmonary edema; and treatment (at entry) with ″-blockers, other antihypertensives, digoxin/antiarrhythmics, or anticoagulants; those in the fish advice group had a significantly lower relative risk of all deaths than those not in the fish advice group ($p<0.05$); similar results were also found in the unadjusted comparison.	

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
He et al., 2004b	Meta-analysis	13 cohort studies from 11 independent studies English language 222,364 participants 3032 coronary heart disease deaths Average of 11.8 years of follow-up Primary prevention	Seafood

Amount	Results	Conclusion**
Categories of fish intake: 1 = Never-<1 time/month 2 = 1-3 times/month 3 = 1 time/week 4 = 2-4 times/week 5 = ε5 times/week	Based on pooled relative risks of CHD mortality, those who ate fish 1 time/week, 2-4 times/week, and ε5 times/week had significantly lower risk of CHD mortality than those who never ate fish (RR=0.85, 95% CI 0.76-0.96; RR=0.77, 95% CI 0.66-0.89; RR=0.62, 95% CI 0.46-0.82, respectively). Those who ate fish 1-3 times/month also had a lower relative risk compared to those who never ate fish, but it was not significant (RR=0.89, 95% CI 0.79-1.01). "Each 20-g/day increase in fish intake was related to a 7% lower risk of CHD mortality (p for trend = 0.03)."	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Whelton et al., 2004	Meta-analysis	14 cohort studies 5 case-control studies Conducted in adult humans English language Published before May 2003 Primary and secondary prevention	Seafood

Amount	Results	Conclusion**
Consumed fish on a regular basis vs. consumed little or no fish Level of fish consumption: <2, 2-<4, ε4 portions per week	In 6 cohort studies, those consuming any amount of fish had a significantly lower risk of coronary heart disease mortality compared to those who ate no fish; in seven cohort studies no significant associations were found between fish consumption and coronary heart disease mortality. Based on pooled estimates from a random-effects model, those who ate any fish (pooled RR=0.83, 95% CI 0.76-0.90), those who ate <2 portions of fish/week (pooled RR=0.83, 95% CI 0.75-0.92), and those who ate 2- <4 portions of fish/week (pooled RR=0.75, 95% CI 0.62-0.92) had a significantly lower risk of coronary heart disease mortality compared to those who ate no fish; a significant difference was not found between those who ate ε4 portions of fish/week and those who never ate fish. In one cohort study and five case-control studies those consuming any amount of fish had a significantly lower risk of total coronary heart disease compared to those who ate no fish; in one cohort study, those who ate fish had a significantly higher risk of total coronary heart disease compared to those who ate no fish (RRH1.8, 95% CI 1.2-3.2); in five cohort studies no significant associations were found between fish consumption and total coronary heart disease. Based on pooled estimates from a random-effects model, those who ate any fish (pooled RR=0.86, 95% CI 0.81-0.92), those who ate <2 portions of fish/week (pooled RR=0.85, 95% CI 0.80-0.91), and those who ate 2- <4 portions of fish/week (pooled RR=0.83, 95% CI 0.69-0.99) had a significantly lower risk of total coronary heart disease compared to those who ate no fish; a significant difference was not found between those who ate ε4 portions of fish/week and those who never ate fish.	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Calder, 2004	Review	Primary and secondary prevention studies in humans (n=25)	Seafood or n-3 supplement
Marckmann and Gronbaek, 1999	Review	Prospective cohort studies (n=9) Letter (n=1) Short report (n=1) Sample size and length of follow-up varied between studies Primary prevention	Seafood

Amount	Results	Conclusion**
	"Substantial evidence from epidemiological and case-control studies indicates that consumption of fish, fatty fish, and long-chain n-3 PUFAs reduces the risk of cardiovascular mortality."	B
	"Secondary prevention studies using long-chain n-3 PUFAs in patients post-myocardial infarction have shown a reduction in total and cardiovascular mortality."	
	"Long-chain n-3 PUFAs have been shown to decrease blood triacylglycerol (triglyceride) concentrations, to decrease production of chemoattractants, growth factors, adhesion molecules, inflammatory eicosanoids and inflammatory cytokines, to lower blood pressure, to increase nitric oxide production, endothelial relaxation and vascular compliance, to decrease thrombosis and cardiac arrhythmias and to increase heart rate variability."	
	Both Krohout (1985) and Daviglus (1997) showed a significant inverse relationship between fish intake (g/day) and risk of coronary heart disease (p for trend <0.05 and p for trend = 0.04, respectively).	N
	"Our overall conclusion is that individuals at low risk of CHD and with healthy lifestyles do not gain any additional protection against CHD from eating fish. On the other hand, high-risk individuals appear to benefit in a dose-dependent manner from increasing their fish consumption up to an optimum of 40-60 g."	

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Iso et al., 2006	Cohort	Men (n=19,985) Women (n=21,593) Aged 40-59 years Japan (Iwate Prefecture, Akita, Nagano, Okinawa) The Japan Public Health Center-based Study Cohort I No myocardial infarction, angina pectoris, stroke, or cancer at baseline 477,325 person-years of follow-up Primary prevention	Seafood

Amount	Results	Conclusion**
One serving = 100 g for fresh fish, 20 g for dried or salted fish, 20 g for salted fish roe, 20 g for salted fish preserves n-3 amounts per serving = 1.22 g for fresh fish and shellfish, 0.40 g for dried fish, 0.52 g for salted eggs, and 0.11 g for salted fish gut Quintiles of fish and n-3 intakes: 1 (low) = mean of 23 g/day 2 = mean of 51 g/day 3 = mean of 78 g/day 4 = mean of 114 g/day 5 (high) = mean of 180 g/day	After adjusting for age; sex; cigarette smoking; alcohol intake; BMI; histories of hypertension and diabetes; medication use for hypercho - lesterolemia; education level; sports at leisure time; quintiles of dietary intake of fruits, vegetables, saturated fat, monounsaturated fat, n-6 polyunsaturated fat, cholesterol; total energy; and public health center: Those in the 5th quintile of fish intake had a significantly lower HR of definite MI (HR=0.44, 95% CI 0.24-0.81) and nonfatal coronary events (HR=0.43, 95% CI 0.23-0.81) than those in the 1st quintile. Those in the 2nd, 3rd, and 4th quintiles also had lower hazard ratios of definite MI and nonfatal coro - nary events, but they were not significant; No significant associations were found between quintiles of fish intake and coronary heart disease, total MI, sudden cardiac death, or fatal coronary events; Those in the 5th quintile of n-3 intake had significantly lower HRs of coronary heart disease (HR=0.58, 95% CI 0.35-0.97), total MI (HR=0.43, 95% CI 0.24-0.78), definite MI (HR=0.35, 95% CI 0.18-0.66), and nonfatal coronary heart disease (HR=0.33, 95% CI 0.17-0.63) than those in the 1st quintile; Those in the 4th quintile of n-3 intake had a significantly lower HR of nonfatal coronary events (HR=0.57, 95% CI 0.34-0.98) than those in the 1st quintile. However, there were no significant associations found between n-3 intake and coronary heart disease, total MI, or definite MI, sudden cardiac death, or fatal coronary events when comparing the 4th quintile to the 1st quintile; and Those in the 3rd quintile of n-3 intake had sig - nificantly lower HRs of definite MI (HR=0.59, 95% CI 0.37-0.94) and nonfatal coronary events (HR=0.61, 95% CI 0.38-0.97) than those in the 1st quintile. However, there were no significant associations found between n-3 intake and coronary heart disease, total MI, sudden cardiac death, or fatal coronary events when comparing the 3rd quintile to the 1st quintile.	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Mozaffarian et al., 2004	Cohort	Men and women (n=4815) Aged ε65 years From Medicare eligibility lists in 4 US communities Cardiovascular Health Study (CHS) Free of atrial fibrillation at baseline Follow-up of 12 years Primary prevention	Seafood

Amount	Results	Conclusion**
Categories of fish intake (tuna/other or fried fish/fish sandwich): 1 = <1 time/month 2 = 1-3 times/month 3 = 1-4 times/week 4 = ε5 times/week	After adjusting for age, gender, race, education, diabetes, BMI, prevalent coronary heart disease, prevalent valvular heart disease, smoking status, pack-years of smoking, leisure-time activity, total caloric intake, alcohol, saturated fat, beef/pork, fruits, vegetables, cereal fiber, systolic blood pressure, diastolic blood pressure, left ventricular systolic function at baseline, treated hypertension, C-reactive protein: Those who ate tuna/other fish 1-4 times/week or ε5 times/week had significantly lower HR of atrial fibrillation than those who ate tuna/other fish <1 time/month (HR=0.72, 95% CI 0.57-0.90 and HR=0.70, 95% CI 0.53-0.93, respectively). Those who ate tuna/other fish 1-3 times/month also had a lower HR of atrial fibrillation than those who ate tuna/other fish <1 time/month, but it was not significant. There was no significant association found between fried fish/fish sandwich intake and the risk of atrial fibrillation.	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Mozaffarian et al., 2003	Cohort	Men and women (n=3910) Aged ε65 years From Medicare eligibility lists in 4 US communities Cardiovascular Health Study (CHS) Free from CVD at baseline Follow-up of 9.3 years Primary prevention	Seafood

Amount	Results	Conclusion**
Categories of fish intake (tuna/other or fried fish/fish sandwich): 1 = <1 time/month 2 = 1-3 times/month 3 = 1 time/week 4 = 2 times/week 5 = ε3 times/week	After adjusting for age, gender, education, diabetes, current smoking, pack-years of smoking, BMI, systolic blood pressure, LDL-C, HDL-C, triglycerides, C-reactive protein, and intake of saturated fat, alcohol, beef/pork, fruits, and vegetables: Those who ate tuna/other fish 2 times/week and ε3 times/week had a significantly lower RR of total IHD death than those who ate tuna/other fish <1 time/month (RR=0.53, 95% CI 0.30-0.96 and RR=0.47, 95% CI 0.27-0.82, respectively). Those who ate tuna/other fish 1-3 times/month and 1 time/week also had lower RR of total IHD death compared to those who ate tuna/other fish <1 time/month, but they were not significant; Those who ate tuna/other fish ε3 times/week had a significantly lower RR of arrhythmic IHD death than those who ate tuna/other fish <1 time/month (RR=0.32, 95% CI 0.15-0.70). The other categories of intake also showed lower RR of arrhythmic IHD death compared to the 1st category of intake but they were not significant; and There were no significant associations found between tuna/other fish intake and nonfatal MI and between fried fish/fish sandwiches and total IHD death, arrhythmic IHD death, or nonfatal MI. After adjusting for age, gender, education, diabetes, current smoking, and pack-years of smoking: Those who ate tuna/other fish ε3 times/week had a significantly lower RR of total IHD death and arrhythmic IHD death than those who ate tuna/other fish <1 time/month (RR=0.51, 95% CI 0.31-0.83 and RR=0.42, 95% CI 0.21-0.84, respectively). There were no other significant associations found between the other categories of tuna/other fish intake and the risk of death from total IHD, arrhythmic IHD, or nonfatal MI; and Those who ate fried fish/fish sandwiches ε3 times/week had a significantly higher RR of nonfatal MI death than those who ate fried fish/fish sandwiches <1 time/month (RR=2.30, 95% CI 1.18-4.46). There were no other sig - nificant associations found between the other categories of fried fish/fish sandwich intake and the risk of death from total IHD, arrhyth - mic IHD, or nonfatal MI.	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Osler et al., 2003	Cohort	Men (n=4513) Women (n=3984) Aged 30-70 years Copenhagen County, Denmark general population MONICA 1 = born in 1922, 1932, 1942, or 1952; examined in 1982 MONICA 2 = born in 1927, 1937, 1947, or 1957; examined in 1987 MONICA 3 = born in 1922, 1932, 1942, 1952, or 1962; examined in 1992 No CHD in the preceding 5 years before enrollment (fatal or nonfatal CHD as an end point) 52,607 person-years of follow-up for men 48,596 person-years of follow-up for women Primary prevention	Seafood

Amount	Results	Conclusion**
Categories of fish intake: 1 = Never 2 = δ1 time/month 3 = 2 times/month 4 = 1 time/week 5 = ε2 times/week	After adjusting for smoking status, physical activity, alcohol, educational status, healthy diet score, total cholesterol, total cholesterol, BMI: Those who consumed fish 2 times/month had a significant lower HR of all-cause mortality compared to those who ate fish 1 time/week (HR=0.84, 95% CI 0.73-0.96). No other significant differences were found between categories of fish consumption and all-cause mortality, CHD mortality and morbidity, and CHD mortality.	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Hu et al., 2002	Cohort	Women (n=84,688) Aged 30-55 years Nurses living in the United States Nurses' Health Study Exclude those who left 10 or more items blank on the dietary questionnaire, those with reported total food intakes judged to be implausible, and those who had a history of cancer, angina, myocardial infarction, coronary revascularization, stroke, or other cardiovascular disease at baseline Follow-up of 16 years Primary prevention	Seafood

Amount	Results	Conclusion**
Serving sizes: Dark-meat fish = 3-5 oz (1.51 g EPA/DHA) Canned tuna = 3-4 oz (0.42 g EPA/DHA) Other fish = 3-5 oz (0.48 g EPA/DHA) Shrimp/lobster/scallops = 3.5 oz (0.32 g EPA/DHA) Categories of fish intake: 1 = <1 time/month 2 = 1-3 times/month 3 = 1 time/week 4 = 2-4 times/week 5 = ε5 times/week	After adjusting for age, time periods, smoking status, BMI, alcohol intake, menopausal status and postmenopausal hormone use, vigorous to moderate activity, number of times aspirin was used per week, multivitamin use, vitamin E supplement use, history of hypertension, hypercholesterolemia, diabetes, and intake of transfat, the ratio of polyunsaturated fat to saturated fat, and dietary fiber: Those in categories 2-5 of fish intake all had significantly lower RR of coronary heart disease compared to those in category 1 (RR=0.79, 95% CI 0.64-0.97; RR=0.72, 95% CI 0.59-0.88; RR=0.72, 95% CI 0.57-0.91; RR=0.69, 95% CI 0.52-0.93, respectively) (p for trend = 0.007); Those in categories 3 and 5 of fish intake had significantly lower RR of fatal CHD compared to those in category 1 (RR=0.65, 95% CI 0.46-0.91 and RR=0.55, 95% CI 0.33-0.91, respectively). Those in categories 2 and 4 also had lower RRs but they were not significant (p for trend = 0.01); and Those in categories 3 and 4 had significantly lower RR of nonfatal MI compared to those in category 1 (RR=0.75, 95% CI 0.59-0.96 and RR=0.71, 95% CI 0.53-0.96, respectively). Those in categories 2 and 5 also had lower RRs but they were not significant (p for trend = 0.10); and Similar results were found when the model did not also adjust for intake of transfat, the ratio of polyunsaturated fat to saturated fat, and dietary fiber.	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Nagata et al., 2002	Cohort	Men (n=13,355) Women (n=15,724) Aged 35 years or older Takayama, Gifu, Japan No history of cancer, stroke, or ischemic heart disease Follow-up of 7 years (201,160 person-years) Primary prevention	Seafood or n-3 supplement

Amount	Results	Conclusion**
Quintiles of fish intake (median g/day): Quintile 1 = 46.2 for men, 36.6 for women Quintile 2 = 68.1 for men, 53.9 for women Quintile 3 = 86.8 for men, 68.8 for women Quintile 4 = 111.9 for men, 88.1 for women Quintile 5 = 157.8 for men, 122.4 for women Quintiles of fish oil intake (medium mg/day): Quintile 1 = 410 for men, 332 for women Quintile 2 = 602 for men, 486 for women Quintile 3 = 788 for men, 635 for women Quintile 4 = 1051 for men, 832 for women Quintile 5 = 1582 for men, 1253 for women	After adjusting for age, total energy intake, marital status, BMI, smoking status, alcohol intake, coffee intake, exercise, and history of hypertension and diabetes mellitus: There were no significant associations between quintiles of fish intake and risk of all-cause mortality among men or women; Men in the 2nd quintile of fish oil intake had a significantly lower HR of all-cause mortality than men in the 1st quintile of fish oil intake (HR=0.82, 95% CI 0.67-0.99). Men in the higher quintiles of fish oil intake also had lower HR of all-cause mortality compared to men in the 1st quintile of fish oil intake, but they were not significant; and Women in the 5th quintile of fish oil intake had a significantly lower HR of all-cause mortality than women in the 1st quintile of fish oil intake (HR=0.77, 95% CI 0.62-0.94). Women in the other quintiles of fish oil intake also had lower HR of all-cause mortality compared to women in the 1st quintile of fish oil intake, but they were not significant. There were no significant associations found between quintiles of fish oil intake and cardiovascular disease mortality among men or women.	N

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Yuan et al., 2001	Cohort	Men (n=18,244) Aged 45-64 years Shanghai, China No history of cancer Follow-up of 12 years (179,466 person-years) Primary prevention	Seafood

Amount	Results	Conclusion**
Fresh fish = 0.57 g n-3 fatty acids/100 g Salted fish = 0.44 g n-3 fatty acids/100 g Shellfish = 0.36 g n-3 fatty acids/100 g	After controlling for age, total energy intake, level of education, BMI, current smoker at recruitment, average number of cigarettes smoked/day, number of alcoholic drinks consumed/week, history of diabetes, and history of hypertension:	B
Fish and shellfish categories (g/week): 1 = <50 (<1 serving/week) 2 = 50-<100 (1 serving/week) 3 = 100-<150 (2 servings/week) 4 = 150-<200 (3 servings/week) 5 = ε200 (ε4 servings/week)	Those in the 2nd and 5th categories of fish/shellfish intake had significantly lower RR of acute myocardial infarction mortality than those in the 1st category (RR=0.55, 95% CI 0.33-0.91 and RR=0.41, 95% CI 0.22-0.78, respectively) (p for trend = 0.03). Similar results were found for the categories of fish only, but there were no associations found between shellfish only and risk of acute myocardial infarction mortality; and	
Quintiles of n-3 fatty acid intake (g/week): 1 = <0.27 2 = 0.27-0.43 3 = 0.44-0.72 4 = 0.73-1.09 5 = ε1.10	Those in the 2nd, 4th, and 5th quintiles of n-3 fatty acid intake had significantly lower RR of acute myocardial infarction mortality than those in the 1st quintile (RR=0.39, 95% CI 0.20-0.75; RR=0.53, 95% CI 0.29-0.97; RR=0.43, 95% CI 0.23-0.81, respectively). Those in the 3rd quintile also had a lower RR compared to the 1st quintile, but it was not significant (RR=0.67, 95% CI 0.42-1.08). There were no significant associations between fish intake and other ischemic heart disease mortality or stroke mortality or between n-3 fatty acid intake and other ischemic heart disease mortality.	

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Gillum et al., 2000	Cohort	Men and women (n=8825) White (n=7421) Black (n=1404) Aged 25-74 years US general population (civilian, non-institutionalized) excluding Alaska, Hawaii, and reservation lands of American Indians National Health and Nutrition Examination Survey (NHANES) I Epidemiologic Follow-up Study No history of heart disease at baseline No unknown baseline fish consumption, systolic blood pressure, serum cholesterol concentration, history of diabetes, cigarette smoking status, alcohol intake, body mass index, history of heart disease, nonrecreational physical activity, or educational attainment Average follow-up of 18.8 years Primary prevention	Seafood
Oomen et al., 2000	Cohort	Men Aged 50-69 years Finland (n=1088), Italy (n=1097), Netherlands (n=553) cohorts of the Seven Countries Study Free of CHD at baseline Follow-up of 20 years Primary prevention	Seafood

Amount	Results	Conclusion**
Categories of fish consumption: 1 = Never 2 = <1 occasion/week 3 = 1 occasion/week 4 = >1 occasion/week	After adjusting for baseline age, smoking, history of diabetes, education < high school graduate, systolic blood pressure, serum cho - lesterol concentration, BMI, alcohol intake, and physical activity: Among White men, those who ate fish 1 occasion/week had a significantly lower RR of all-cause mortality (RR=0.76, 95% CI 0.63-0.91) and noncardiovascular disease mortality (RR=0.68, 95% CI 0.53-0.88) compared to those who never ate fish. No other compari - sons between categories of fish consumption, and all-cause, cardiovascular disease, or noncardiovascular disease, mortality were significant; There were no significant associations found between fish intake and all-cause, cardiovas - cular disease, and noncardiovascular disease mortality among Black men, White women, or Black women; and There were no significant associations found between fish intake and incidence of coronary heart disease among White or Black men or women.	B
Finland fish consumption: 1 = 0-19 g/day 2 = 20-39 g/day 3 = ε40 g/day Italy fish consumption: 1 = 0 g/day 2 = 1-19 g/day 3 = 20-39 g/day 4 = ε40 g/day Netherlands fish consumption: 1 = 0 g/day 2 = 1-19 g/day 3 = ε20 g/day	After adjusting for age, BMI, cigarette smok - ing, and intake of energy, vegetables, fruit, alcohol, meat, butter, and margarine, there were no significant associations found between total fish consumption and the risk of 20-year CHD mortality in any of the three countries. Similar results were found when the model did not adjust for intake of vegetables, fruit, alcohol, meat, butter, and margarine. After stratifying by country cohort and pool - ing the data, the overall RR for CHD mortal - ity for intake of 1-19 g/day of fatty fish was 0.57 (95% CI 0.40-0.80) and for intake of ε20 g/day of fatty fish was 0.87 (95% CI 0.59-1.27) compared to no fatty fish consumption.	N

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Albert et al., 1998	Cohort	Men (n=20,551) Aged 40-84 years US physicians Physicians' Health Study Free of MI, stroke, transient ischemic attack, or cancer at baseline 2-by-2 factorial design to receive aspirin, beta carotene, both active drugs, or both placebo 11 years of follow-up (253,777 person-years) Primary prevention	Seafood

Amount	Results	Conclusion**
Categories of fish intake: <1 meal per month 1-3 meals per month 1-<2 meals per week 2-5 meals per week ε5 meals per week	After adjusting for age, those who ate fish 1-<2 meals per week, 2-<5 meals per week, and ε5 meals per week had a significantly lower RR of sudden death than those who ate fish only <1 per month (RR=0.42, 95% CI 0.21-0.88; RR=0.46, 95% CI 0.23-0.93; RR=0.34, 95% CI 0.14-0.83, respectively) (p for trend = 0.03). After combining the higher quartiles of fish consumption, those who ate fish ε1 per week had a significantly lower relative risk of sud - den death than those who ate fish only <1 per month (RR=0.44, 95% CI 0.22-0.86) (p for trend = 0.006). After adjusting for age, aspirin, and beta carotene treatment assignment, evidence of cardiovascular disease prior to 12-month questionnaire, BMI, smoking status, history of diabetes, history of hypertension, history of hypercholesterolemia, alcohol consumption, vigorous exercise, and vitamin E, vitamin C, and multivitamin use: Those who ate fish 1-<2 meals per week and ε5 meals per week had a significantly lower RR of sudden death than those who ate fish only <1 per month (RR=0.47, 95% CI 0.23-0.98 and RR=0.39, 95% CI 0.15-0.96, respectively) (p for trend = 0.11); and After combining the higher quartiles of fish consumption, those who ate ε1 fish meal per week had a significantly lower RR of sudden death than those who ate only <1 fish meal per month (RR=0.48, 95% CI 0.24-0.96) (p for trend = 0.03).	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Daviglus et al., 1997	Cohort	Men (n=1822) Aged 40-55 years Chicago, IL Employed for at least 2 years at the Western Electric Company Hawthorne Works in Chicago; occupations related to manufacturing telephones Chicago Western Electric Study Free of CVD at baseline Follow-up of 30 years Primary prevention	Seafood
Mann et al., 1997	Cohort	Men (n=4102) Women (n=6700) Vegetarians and their nonvegetarian friends and family Aged 16-79 years UK No cancer at entry Excluded those who failed to provide full information concerning smoking habits, height, weight, and employ - ment category Follow-up of 13.3 years (over 143,000 person-years) Primary prevention	Seafood
Rodriquez et al., 1996	Cohort	Men (n=3310) Aged 45-68 years Oahu, Hawaii Japanese ancestry Current smokers Honolulu Heart Program Free of CHD, stroke, cancer at baseline Follow-up of 23 years Primary prevention	Seafood

Amount	Results	Conclusion**
Categories of fish intake: 1 = 0 g/day 2 = 1-17 g/day 3 = 18-34 g/day 4 = ε35 g/day	After controlling for baseline age and education, religion, systolic blood pressure, serum cholesterol, number of cigarettes smoked per day, BMI, presence or absence of diabetes, presence or absence of electrocardiographic abnormalities, and daily intake of energy, cholesterol, saturated, monounsaturated, and polyunsaturated fatty acids, total protein, carbohydrate, alcohol, iron, thiamine, riboflavin, niacin, vitamin C, beta carotene, and retinol: Those who consumed fish had a lower relative risk of death from MI, CVD, CHD, and all causes. However, the only significant differences were between the 4th category of fish consumption compared to the 1st category for death from overall MI (RR=0.56, 95% CI 0.33-0.93), all CHD (RR=0.62, 95% CI 0.40-0.94), and nonsudden death from MI (RR=0.33, 95% CI 0.12-0.91).	B
Categories of fish intake: 1 = None 2 = <1 time/week 3 = ε1 time/week	After adjusting for age, sex, smoking, and social class, there were no significant associations found between fish intake and the risk of death from ischemic heart disease or all causes (for those with no evidence of preexisting disease at the time of recruitment).	N
Categories of fish intake: 1 = Almost never 2 = <2 times/week 3 = 2-4 times/week 4 = Almost daily 5 = >1 time/day Low = <2 times/week High = ε2 times/week	After adjusting for age, years lived in Japan, total calories/day, alcohol intake, physical activity, years smoked, hypertension, and serum cholesterol, glucose, and uric acid levels: In the high-smoking group, those with high fish intake had a significantly lower risk of CHD mortality compared to those with low fish intake (RR=0.5, 95% CI 0.28-0.91). There was no significant association found between fish intake and CHD mortality among past smokers (p=0.6).	N

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Ascherio et al., 1995	Cohort	Men (n=44,895) Aged 40-75 years US health professionals Health Professional Follow-up Study Free of known CVD at baseline; no previous diagnosis of MI, angina, stroke, transient ischemic attack, peripheral arterial disease, or had undergone coronary artery surgery 6 years of follow-up (242,029 person-years) Primary prevention	Seafood

Amount	Results	Conclusion**
Quintiles of n-3 fatty acids (g/day): 0.01-0.11, 0.12-0.19, 0.20-0.28, 0.29-0.41, 0.42-6.52 Category of fish intake: 1 = <1 time/month 2 = 1-3 times/month 3 = 1 time/week 4 = 2-3 times/week 5 = 4-5 times/week 6 = ε6 times/week	There were no significant associations found between dietary intake of n-3 fatty acids and the risk of coronary artery bypass grafting, nonfatal MI, fatal CHD, any MI, or any CHD. After controlling for age, those in the 4th category of fish intake had a significantly lower RR of nonfatal MI compared to those in the 1st category (RR=0.65, 95% CI 0.45-0.94). Those in the 2nd, 4th, and 5th categories of fish intake had significantly lower RR of any MI compared to those in the 1st category (RR=0.67, 95% CI 0.46-0.99; RR=0.69, 95% CI 0.51-0.94; RR=0.65, 95% CI 0.47-0.92, respectively). After controlling for age, BMI, smoking habits, alcohol consumption, history of hypertension, history of diabetes, history of hypercholesterolemia, family history of MI before 60 years of age, and profession: Those in the 5th and 6th categories of fish intake had a significantly higher RR of coronary artery bypass grafting than those in the 1st category (RR=1.71, 95% CI 1.09-2.68 and RR=1.65, 95% CI 1.03-2.64, respectively); Those in the 2nd and 4th categories of fish intake had a significantly lower RR of nonfatal MI than those in the 1st category (RR=0.62, 95% CI 0.39-1.00 and RR=0.67, 95% CI 0.46-0.97, respectively); Those in the 5th category of fish intake had a significantly lower relative risk of fatal CHD than those in the 1st category (RR=0.54, 95% CI 0.29-1.00); Those in the 2nd, 4th, and 5th categories of fish intake had a significantly lower RR of any MI than those in the 1st category (RR=0.66, 95% CI 0.44-0.97; RR=0.69, 95% CI 0.51-0.94; RR=0.65, 95% CI 0.46-0.92, respectively); and No other significant associations were found between fish intake and CHD.	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Kromhout et al., 1995	Cohort	Men (n=137) Women (n=135) Aged 64-87 years for men Aged 64-85 years for women Rotterdam, Netherlands All patients of the same general practice Follow-up of 17 years Primary prevention	Seafood
Salonen et al., 1995	Cohort	Men (n=1833) Aged 42, 48, 54, or 60 years Eastern Finland Kuopio Ischaemic Heart Disease Risk Factor Study (KIHD) No CHD, history of cerebrovascular stroke, claudication, or cancer at baseline Mean follow-up time for AMI for individuals of 5 years Mean follow-up time for death of 6 years Primary prevention	Seafood

Amount	Results	Conclusion**
Fish intake = yes or no	After adjusting for age, gender, prevalence of MI and angina pectoris, systolic blood pressure, total cholesterol, smoking, alcohol and energy intake/body weight, those who ate fish had a significant lower RR of CHD mortality than those who did not eat fish (RR=0.51, 95% CI 0.29-0.89). The difference in CHD mortality between the fish eaters and the non-fish eaters became apparent after 5 years of follow-up.	B
Continuous variable = g/day Binary variable = <30 or ε30 g/day	After adjusting for age, examination year, ischemic exercise ECG, and maximal oxygen uptake, family history of CHD, cigarette-years, mean systolic blood pressure, diabetes, socioeconomic status, place of residence, dietary iron intake, and serum apolipoprotein B, HDL-cholesterol, and ferritin concentrations: Each one unit (g/day) increase in fish intake significantly increased the risk of fatal or nonfatal AMI (RR=1.004, 95% CI 1.001-1.007). There were no significant associations between fish intake (as a continuous variable) and death from CHD, CVD, or all causes; and Those who consumed ε30 g/day of fish had a significantly higher risk of fatal or nonfatal AMI compared to those who consumed >30 g/day (RR=1.87, 95% CI 1.13-3.09). There was no significant association found between fish intake ε30 g/day and CHD, CVD, or all-cause mortality. Similar results were found when the model only adjusted for age, examination year, ischemic exercise ECG, and maximal oxygen uptake.	A

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Dolecek, 1992	Cohort (nested in an RCT)	Men (n=6250) Aged 35-57 years 22 US clinical centers Multiple Risk Factor Intervention Trial (MRFIT) Only included those in the usual care group for this analysis At high risk of developing CHD because of smoking status, diastolic blood pressure, and serum cholesterol levels Follow-up of 10.5 years Primary prevention	Seafood
Fraser et al., 1992	Cohort	Men and women (n=26,473) Mean age 51 years (men) Mean age 53 years (women) California Non-Hispanic White Adventists The Adventist Health Study No history of heart disease or diabetes at baseline; almost no current smokers (although some past smokers) Follow-up of 6 years Primary prevention	Seafood

Amount	Results	Conclusion**
Quintiles of fish n-3s: Quintile 1 = mean of 0.000 g Quintile 2 = mean of 0.009 g Quintile 3 = mean of 0.046 g Quintile 4 = mean of 0.153 g Quintile 5 = mean of 0.664 g	After adjusting for age, race, smoking, baseline diastolic blood pressure, high density lipopro - tein, low density lipoprotein, and alcohol: A one-unit increase in fish n-3 consumption, expressed in grams, significantly decreased one's risk of CVD mortality (β=−0.9598, $p<0.01$) and CHD mortality (β=−0.93388, $p<0.05$); however there were no significant associations found between fish n-3 consump - tion and risk of mortality from cancer or all causes; and A one-unit increase in fish n-3 consumption, expressed as % kcal, significantly decreased one's risk of CVD mortality (β=−0.4499, $p<0.01$), CHD mortality (β=−0.4715, $p<0.05$), and all-cause mortality (β=−0.2590, $p<0.05$); however there was no significant association found between fish n-3 consumption and risk of mortality from cancer.	B
Categories of fish intake: 1 = None 2 = 0<x<1 time/week 3 = ε1 time/week	After stratifying for age, sex, smoking, exer - cise, relative weight, and high blood pressure, no significant RRs were found for definite nonfatal MI, definite fatal CHD, or fatal CHD as determined by death certificate, based on fish intake. However, there seemed to be a trend of lower RRs for higher intakes of fish.	N

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Kromhout et al., 1985	Cohort	Men (n=852) Aged 40-59 years Zutphen, Netherlands The Zutphen Study (Dutch contribution to the Seven Countries Study) Free of CHD at baseline Follow-up of 20 years Primary prevention	Seafood

Amount	Results	Conclusion**
Categories of fish intake: 1 = 0 g/day 2 = 1-14 g/day 3 = 15-29 g/day 4 = 30-44 g/day 5 = ε45 g/day	After adjusting for age, systolic blood pres - sure, serum total cholesterol, cigarette smok - ing, subscapular skinfold thickness, physical activity, energy intake, dietary cholesterol, prescribed diet, and occupation: Those in category 4 of fish intake had a significantly lower RR of death from coronary heart disease than those in the 1st category (RR=0.36, 95% CI 0.14-0.93); and Those in the 2nd, 3rd, and 5th fish consump - tion categories also had lower RRs of death from coronary heart disease than those in the 1st category, but they were not significant (p for trend = <0.05).	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Albert et al., 2002	Case-control (nested)	Cases (n=94) = sudden death occurred (first manifestation of CVD) Controls (n=184) = free of confirmed CVD Men Aged 40-84 years US physicians Physicians' Health Study Free of MI, stroke, transient ischemic attacks, or cancer at baseline 2-by-2 factorial design to receive aspirin, beta carotene, both active drugs, or both placebo 17 years of follow-up (time from study enrollment to sudden death = 0.7-16.9 years) Primary prevention	Baseline blood fatty acid levels

Amount	Results	Conclusion**
Quartiles of n-3 fatty acids (% total fatty acids): 2.12-4.32, 4.33-5.19, 5.20-6.07, 6.08-10.2	After adjusting for age and smoking status: The RR of sudden death was significantly lower for those in the 3rd and 4th quartiles of n-3 fatty acid intake (RR=0.37, 95% CI 0.17-0.83 and RR=0.31, 95% CI 0.13-0.75, respectively) compared to those in the 1st quartile (p for trend = 0.004). After adjusting for assignment to aspirin and beta carotene treatment or placebo, BMI, history of diabetes, history of hypertension, history of hypercholesterolemia, alcohol con - sumption, frequency of vigorous exercise and parental history of MI before the age of 60: The RR of sudden death was significantly lower for those in the 3rd and 4th quartiles of n-3 fatty acid intake (RR=0.28, 95% CI 0.09-0.87 and RR=0.19, 95% CI 0.05-0.71, respectively) compared to those in the 1st quartile (p for trend = 0.007). After adjusting for assignment to aspirin and beta carotene treatment or placebo, BMI, history of diabetes, history of hypertension, history of hypercholesterolemia, alcohol consumption, frequency of vigorous exercise, parental history of myocardial infarction be - fore the age of 60, trans unsaturated fatty acid and monounsaturated fatty acid levels: The RR of sudden death was significantly lower for those in the 3rd and 4th quartiles of n-3 fatty acids (RR=0.19, 95% CI 0.05-0.69 and RR=0.10, 95% CI 0.02-0.48, respectively) compared to those in the 1st quartile (p for trend = 0.001).	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Martinez-Gonzalez et al., 2002	Case-control	Cases = suffered first definite AMI; admitted to hospital (n=171) Controls = admitted to same hospital during same month for unrelated conditions (n=171) Men and women Aged <80 years Three tertiary hospitals of Pamplona, Spain No history of angina pectoris, a previous diagnosis of CHD, or other prior diagnosis of major cardiovascular disease Secondary prevention	Seafood
Sasazuki et al., 2001	Case-control	Cases = first episode of AMI (n=632) Controls = residents from same municipalities as the cases (n=1214) Men and women Aged 40-79 years 22 collaborating hospitals in Fukuoka City, Japan, and in 21 adjacent municipalities Fukuoka Heart Study Secondary prevention	Seafood

Amount	Results	Conclusion**
Categories of fish intake: 1 = <60 g/day 2 = 60-77 g/day 3 = 77-106 g/day 4 = 106-142 g/day 5 = >142 g/day	After adjusting for age, hospital, gender, smoking, BMI, high blood pressure, high blood cholesterol, diabetes, leisure-time physical activity, socioeconomic status, and total energy: Those in the 3rd and 5th categories of fish intake had significantly lower ORs of first MI compared to those in the 1st category (OR=0.28, 95% CI 0.10-0.77 and OR=0.31, 95% CI 0.11-0.85, respectively). Those in the 2nd and 4th categories of fish intake also had lower ORs compared to those in the 1st category, but they were not significant. Those in the three upper quintiles of fish intake had a significantly lower OR of a first MI compared to those in the lower quintile (OR=0.36, 95% CI 0.15-0.87). After further adjusting for olive oil, fiber, fruits, vegetables, alcohol, meat/meat products, and white bread/rice/pasta intake, this association was not significant (OR=0.37, 95% CI 0.13-1.03).	B
Categories of fish consumption (men and women): Low = <2/week Intermediate = 2-3/week High = 4+/week	After adjusting for smoking, alcohol use, sedentary job, leisure-time physical activity, hyperlipidemia, hypertension, diabetes mellitus, angina pectoris, and obesity: Men who consumed intermediate and high levels of fish had a significantly lower RR of acute MI compared to those who consumed low levels of fish (RR=0.5, 95% CI 0.3-0.8 and RR=0.6, 95% CI 0.4-0.9, respectively); and The relative risks for acute MI based on fish consumption were not significant among women. Similar results were found when also adjusting for fruit and tofu intake.	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Tavani et al., 2001	Case-control	Cases = first episode of nonfatal AMI; admitted to hospital (n=507) Controls = admitted to same hospital for unrelated conditions (n=478) Men and women Aged 25-79 years Greater Milan, Italy area Secondary prevention	Seafood
Siscovick et al., 1995	Case-control	Case = primary cardiac arrest patients (n=334) Controls = from community (n=493) Men and women Aged 25-74 years Married Seattle and suburban King County, WA Free of prior clinical heart disease, major comorbidities, and use of fish-oil supplements On average, 4 months between the date of cardiac arrest and in-person interview Primary prevention	Seafood

Amount	Results	Conclusion**
Mixed Mediterranean fish = 0.94 g of n-3 per portion Other fish = 0.49 g of n-3/portion Canned tuna, mackerel, and sardines = 0.34 g of n-3/portion Categories of n-3 PUFA: Lowest = <0.81 g/week Intermediate = 0.81-1.28 g/week Highest = >1.28 g/week Categories of total fish and fresh fish: 1 = <1 portion/week 2 = 1-<2 portions/week 3 = ε2 portions/week Categories of canned fish: 1 = 0 portions/week 2 = >0-<1 portion/week 3 = ε1 portion/week	After adjusting for age; sex; education; BMI; cholesterol; smoking; coffee, alcohol, meat, vegetables, fruit, and calorie intake; physical activity; hyperlipidemia; diabetes; hyperten - sion; and family history of AMI in first-degree relative: Those who consume an intermediate or high level of n-3 PUFAs had a significantly lower OR of AMI compared to those who consumed a low level of n-3 PUFAs (OR=0.67, 95% CI 0.47-0.96 and OR=0.67, 95% CI 0.47-0.95, respectively). Those who consume two or more portions of total fish/week had a significantly lower OR of AMI compared to those who consume less than one portion/week (OR=0.68, 95% CI 0.47-0.98). Those who consume 1- <2 portions/week of total fish also had a lower OR of AMI than those who consume <1 portion/week, but it was not significant. There were no significant associations found between fresh fish intake and canned fish intake and the risk of AMI. Similar results were found when the model only adjusted for age and sex.	B
Average serving size = 3 oz of fish Quartiles of n-3 fatty acids (g/month): Quartile 1 = 0.12-1.95 Quartile 2 = 1.96-4.05 Quartile 3 = 4.06-7.40 Quartile 4 = 7.41-42.72	After adjusting for age, current smoking, for - mer smoking, family history of MI or sudden death, fat intake scale, hypertension, diabetes mellitus, physical activity, weight, height, and education: Those in quartiles 2, 3, and 4 of dietary n-3 fatty acid intakes all had significantly lower ORs of primary cardiac arrest compared to those who never consumed fish (OR=0.7, 95% CI 0.6-0.9; OR=0.5, 95% CI 0.4-0.8; OR=0.4, 95% CI 0.2-0.7, respectively). Those in the 1st quartile also had a lower OR of primary cardiac arrest compared to those who never consumed fish, but it was not significant.	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Gramenzi et al., 1990	Case-control	Cases = an acute MI (n=287) Controls = acute disorders unrelated to ischemic heart disease (n=649) Women Aged 22-69 years for cases Aged 21-69 years for controls 30 hospitals in northern Italy No chronic or digestive conditions; cardiovascular, malignant, hormonal, or gynecological disease; or any disorder that was potentially related to consumption of alcohol or smoking Primary prevention	Seafood

Amount	Results	Conclusion**
Tertiles of fish intake (# portions/week): Tertile 1 = <1 Tertile 2 = 1 Tertile 3 = >1	After adjusting for age, area of residence, education, smoking, hyperlipidemia, diabetes, hypertension, and BMI, the OR for MI was 0.8 for the 2nd tertile of fish intake and 0.7 for the 3rd tertile of fish intake, compared to the 1st tertile ($p<0.05$). After adjusting for age, area of residence, education, smoking, hyperlipidemia, diabetes, hypertension, BMI, carrots, green vegetables, fresh fruit, meat, ham and salami, butter, total fat score, coffee, and alcohol, the OR for MI was 1.0 for the 2nd tertile of fish intake and 0.8 for the 3rd tertile of fish intake, compared to the 1st tertile, and they were not significant.	B

continued

TABLE B-2a Continued

Author	Study Type	Subjects	Exposure
Bang et al., 1971	Ecological	Men (n=61) Women (n=69) Aged >30 years Eskimos in the northwest coast of Greenland, compared to Danish controls Most are hunters and/or fishermen Primary prevention	Plasma total lipids, lipoproteins, cholesterol, and triglycerides

*Included in Balk E, Chung M, Lichtenstein A, Chew P, Kupelnick B, Lawrence A, DeVine D, Lau J. 2004. *Effects of Omega-↑ Fatty Acids on Cardio↑ascular Risk Factors and Intermediate Markers of Cardio ↑ascular Disease. Summary, E ↑idence Report/Tech nology Assessment No. ↑↑ (Prepared by the Tufts-New England Medical Center E↑idence-based*

Amount	Results	Conclusion**
Total lipids (g/L±SD): Eskimo men = 6.17±0.89 Eskimo women = 6.13±0.88 Danish men = 7.12±1.24 Danish women = 7.29±1.16 Cholesterol (g/L±SD): Eskimo men = 2.33±0.35 Eskimo women = 2.22±0.43 Danish men = 2.73±0.49 Danish women = 2.86±0.49 Triglycerides (g/L±SD): Eskimo men = 0.57±0.28 Eskimo women = 0.44±0.13 Danish men = 1.29±0.62 Danish women = 1.08±0.51 Pre-″-lipoproteins (g/L±SD): Eskimo men = 0.48±0.31 Eskimo women = 0.43±0.33 Danish men = 1.70±0.86 Danish women = 1.08±0.51 ″-lipoproteins (g/L±SD): Eskimo men = 4.38±0.93 Eskimo women = 4.45±0.89 Danish men = 5.11±1.16 Danish women = 5.31±1.32 ±-lipoproteins (g/L±SD): Eskimo men = 4.02±1.39 Eskimo women = 3.91±1.41 Danish men = 2.78±0.82 Danish women = 3.64±0.94	Among males, the Eskimos had significantly lower plasma total lipids ($p<0.001$), cholesterol ($p<0.001$), triglycerides ($p<0.001$), pre-″-lipoproteins ($p<0.001$), ″-lipoproteins ($p<0.001$), and ±-lipoproteins ($p<0.001$) compared to the Danes. However, the differences in total lipids and cholesterol among men 31-40 years and ″-lipoproteins among men 31-50 years between the Eskimos and the Danes were not significant. Among women, the Eskimos had significantly lower plasma total lipids ($p<0.001$), cholesterol ($p<0.001$), triglycerides ($p<0.001$), pre-″-lipoproteins ($p<0.001$), and ″-lipoproteins ($p<0.001$). However, the difference in ″-lipoproteins among women 31-50 years between the Eskimos and the Danes was not significant. There were no significant differences in ±-lipoproteins among the female Eskimos and Danes.	B

Practice Center, Boston, MA). AhRQ Publication No. 0 ⇑-E0⇑0-⇑. Rockville, MD: Agency for Healthcare Research and Quality.

**N = Evidence of no association or no clear association; B = Evidence of a benefit; A = Evidence of an adverse effect.

TABLE B-2b Studies on Stroke

Author	Study Type	Subjects	Exposure
Hooper et al., 2005	Cochrane Review	48 RCTs At least 6 months of omega-3 fatty acids vs. placebo or control 26 cohorts (47 analyses) Follow-up of 4-25 years	n-3 supplement
Bouzan et al., 2005	Meta-analysis	5 cohort studies 1 case-control study	Seafood
He et al., 2004a	Meta-analysis	9 cohorts (from 8 studies) English language	Seafood

Amount	Results	Conclusion**
	Based on RCTs, no significant association was found between omega-3 intake and risk of total stroke based on a meta-analysis (RR=1.17, 95% CI 0.91-1.51) or sensitivity analysis (RR=0.87, 95% CI 0.72-1.04).	N
Servings/week, a continuous variable	In the linear regression model, for each one-unit increase in servings/week of fish, the change in the risk ratio of total stroke is −0.20 (95% CI −0.066 to 0.027), but this is not significant. In the quadratic regression model, for each one-unit increase in servings/week of fish, the change in the risk ratio of total stroke is 0.0037 (95% CI −0.0096 to 0.017), but this is not significant.	N
Categories of fish consumption: 1 = <1 time/month 2 = 1-3 times/month 3 = 1 time/week 4 = 2-4 times/week 5 = ε5 times/week	Based on pooled RRs, those who consumed fish 1 time/week, 2-4 times/week, and ε5 times/week had significantly lower RR of stroke compared to those who consumed fish <1 time/month (RR=0.87, 95% CI 0.77-0.98; RR=0.82, 95% CI 0.72-0.94; and RR=0.69, 95% CI 0.54-0.88, respectively); the RR was not significant for those who consumed fish 1-3 times/month compared to those who consumed fish <1 time/month. Based on pooled RRs, those who consumed fish 1-3 times/month, 1 time/week, 2-4 times/week, and ε5 times/week had significantly lower RR of ischemic stroke compared to those who consumed fish <1 time/month (RR=0.69, 95% CI 0.48-0.99; RR=0.68, 95% CI 0.52-0.88; RR=0.66, 95% CI 0.51-0.87; and RR=0.65, 95% CI 0.46-0.93, respectively). There were no significant associations found between fish consumption and hemorrhagic stroke.	B

continued

TABLE B-2b Continued

Author	Study Type	Subjects	Exposure
Mozaffarian et al., 2005	Cohort	Men and women (n=4778) Aged ε65 years 4 US communities From Medicare eligibility lists Free of known cerebrovascular disease at baseline Cardiovascular Health Study (CHS) 12 years of follow-up	Seafood

Amount	Results	Conclusion**
Categories of tuna/ other fish intake: 1 = <1 time/month 2 = 1-3 times/month 3 = 1-4 times/week 4 = ε5 times/week	After adjusting for age, sex, education, diabetes, coronary heart disease, smoking status, pack-years of smoking, aspirin use, BMI, leisure-time physical activity, alcohol use, total caloric intake, systolic blood pressure, LDL-c, HDL-c, triglyceride, and C-reactive protein levels:	B
Categories for fried fish/fish sandwich intakes: 1 = <1 time/month 2 = 1-3 times/month 3 = ε1 time/week	Those who consumed tuna/other fish 1-4 times/ week had a significantly lower risk of total stroke and ischemic stroke compared to those who con - sumed tuna/other fish <1 time/month (HR=0.74, 95% CI 0.56-0.98 and HR=0.73, 95% CI 0.54-0.98, respectively). Those who consumed tuna/ other fish 1-3 times/month and ε5 times/week also had lower risks of total stroke and ischemic stroke compared to those who consumed tuna/other fish <1 time/month, but they were not significant; Those who consumed fried fish/fish sandwiches ε1 time/week had significantly higher risk of total stroke and ischemic stroke compared to those who consumed fried fish/fish sandwiches <1 time/month (HR=1.33, 95% CI 1.05-1.68 and HR=1.39, 95% CI 1.08-1.79, respectively); and There were no significant associations found be - tween tuna/other fish intake or fried fish/fish sand - wich intake and the risk of hemorrhagic stroke.	

continued

TABLE B-2b Continued

Author	Study Type	Subjects	Exposure
Sauvaget et al., 2003	Cohort	Men (n=14,209) Women (n=22,921) Aged 34-103 years Nagasaki and Hiroshima, Japan The Life Span Study Atomic bomb survivors and their non-exposed controls No prevalent cases of cancer, self-reported cases of stroke, ischemic heart disease, and both stroke and ischemic heart disease Follow-up of 16 years	Seafood

Amount	Results	Conclusion**
Categories of fish intake: 1 = Never 2 = δ1 time/week 3 = 2-4 times/week 4 = Almost daily Tertiles of fish intake: Low = 11-18 g/day Moderate = 30 g/day High = 46-65 g/day	After adjusting for sex, birth cohort, city, radiation dose, self-reported BMI, smoking status, alcohol habits, education level, history of diabetes, and hypertension: There was no significant association found between fish (except broiled) intake and the risk of total stroke mortality, when fish intake was defined as never, δ1 time/week, 2-4 times/week, and almost daily; however, there was a significant trend (p=0.046); Those who ate broiled fish almost daily had a significantly lower RR of total stroke mortal - ity compared to those who never ate broiled fish (HR=0.60, 95% CI 0.37-0.98); Those who ate moderate and high levels of fish products had significantly lower RRs of total stroke (RR=0.85, 95% CI 0.75-0.97 and RR=0.85, 95% CI 0.75-0.98, respectively) and intracerebral hemorrhage (RR=0.70, 95% CI 0.54-0.91 and RR=0.70, 95% CI 0.54-0.92, respec - tively) compared to those who ate low levels of fish products; and There were no significant associations between intake (defined as low, moderate, and high) of fish products and cerebral infarction.	B

continued

TABLE B-2b Continued

Author	Study Type	Subjects	Exposure
He et al., 2002*	Cohort	Men (n=43,671) Aged 40-75 years US health professionals Health Professional Follow-up Study No previously diagnosed stroke, MI, coronary artery surgery, angina pectoris, peripheral arterial disease, diabetes mellitus, transient ischemic attack, or other cardiovascular disease Follow-up of 12 years	Seafood and dietary n-3 fatty acid intake

Amount	Results	Conclusion**
Serving sizes: Dark-meat fish = 3-5 oz (1.60 g n-3) Canned tuna = 3-4 oz (0.41 g n-3) Other fish = 3-5 oz (0.56 g n-3) Shrimp/lobster/scallops = 3.5 oz (0.26 g n-3) Categories of fish intake: 1 = <1 time/month 2 = 1-3 times/month 3 = 1 time/week 4 = 2-4 times/week 5 = ε5 times/week Quintiles of n-3 fatty acids: 1 = <0.05 g/day 2 = 0.05-<0.2 g/day 3 = 0.2-<0.4 g/day 4 = 0.4-<0.6 g/day 5 = ε0.6 g/day	After adjusting for BMI, physical activity, history of hypertension, smoking status, use of aspirin, fish oil, multivitamins, intake of total calories, total fat, saturated fat, trans-unsaturated fat, alcohol, potassium, magnesium, total servings of fruits and vegetables, and hypercholesterolemia at baseline: Those in the higher quintiles of cumulative fish consumption all had significantly lower RR of ischemic stroke compared to those who consumed fish <1 time/month (RR=0.57, 95% CI 0.35-0.95; RR=0.56, 95% CI 0.37-0.84; RR=0.55, 95% CI 0.36-0.85; and RR=0.54, 95% CI 0.31-0.94, respectively); Those in the 4th quintile of cumulative fish intake had a significantly lower RR of total stroke than those in the 1st quintile (RR=0.67, 95% CI 0.46-0.96). The other quintiles also had lower relative risks compared to the 1st quintile, but they were not significant; There were no significant associations found between cumulative fish intake and the risk of hemorrhagic stroke; similar results were found for most recent fish intake; Those in the 2nd, 3rd, and 4th quintiles of n-3 PUFA intake had significantly lower RRs of ischemic stroke compared to those in the first quintile (RR=0.56, 95% CI 0.35-0.88; RR=0.63, 95% CI 0.40-0.98; RR=0.54, 95% CI 0.32-0.91, respectively). Those in the 5th quintile also had a lower RR of ischemic stroke compared to those in the 1st quintile, but it was not significant; and There were no significant associations found between n-3 PUFA intake and total stroke or hemorrhagic stroke.	B

continued

TABLE B-2b Continued

Author	Study Type	Subjects	Exposure
Iso et al., 2001*	Cohort	Women (n=79,839) Aged 34-59 years US nurses Nurses' Health Study No history of cancer, angina, myocardial infarction, coronary revascularization, stroke, other cardiovascular diseases before baseline; or a history of physician-diagnosed diabetes or high serum cholesterol levels Follow-up of 14 years (1,086,261 person-years)	Seafood and dietary n-3 fatty acid intake

Amount	Results	Conclusion**
Serving sizes: Dark-meat fish = 3-5 oz (1.51 g EPA/DHA) Canned tuna = 3-4 oz (0.42 g EPA/DHA) Other fish = 3-5 oz (0.48 g EPA/DHA) Shrimp/lobster/scallops = 3.5 oz (0.32 g EPA/DHA) Categories of fish intake: 1 = <1 time/month 2 = 1-3 times/month 3 = 1 time/week 4 = 2-4 times/week 5 = ε5 times/week Quintiles of n-3 PUFAs (median in grams): 1 = 0.077 g/day 2 = 0.118 g/day 3 = 0.171 g/day 4 = 0.221 g/day 5 = 0.481 g/day	After adjusting for Joules, BMI, alcohol intake, menopausal status and postmenopausal hormone use, vigorous exercise, usual aspirin use, multivita - min use, history of hypertension, and frequency of total fruit and vegetable intake and for intake of saturated fat, trans-unsaturated fat, linoleic acid, animal protein, and calcium: Those who consume 2-4 servings of fish/week had a signficantly lower RR of thrombotic infarction than those who ate fish <1 time/month (RR=0.52, 95% CI 0.27-0.99). Although all other categories of higher fish consumption had lower RRs of thrombotic infarction than the 1st category, they were not significant; Those who ate fish 2 or more times per week had sigificantly lower RR of lacunar infarction than those who ate fish <1 time/month (RR=0.28, 95% CI 0.12-0.67). Although all other categories of higher fish consumption had lower RRs of lacunar infarction than the 1st category, they were not significant; There were no significant associations found between fish consumption and total stroke, ischemic stroke, large-artery occlusive infarction, hemorrhagic stroke, subarachnoid hemorrhage, or intraparenchymal hemorrhage; Those in quintile 3 of omega-3 PUFA intake had a significantly lower RR of total stroke (RR=0.69, 95% CI 0.53-0.89), ischemic stroke (RR=0.67, 95% CI 0.47-0.98), and thrombotic infarction (RR=0.64, 95% CI 0.43-0.95) compared to those in quintile 1; Those in quintile 5 of omega-3 PUFA intake had a significantly lower RR of total stroke (RR=0.72, 95% CI 0.53-0.99) and lacunar infarction (RR=0.37, 95% CI 0.19-0.73) compared to those in quintile 1; and There were no significant associations found between omega-3 PUFA intake and large-artery occlusive infarction, hemorrhagic stroke, sub - arachnoid hemorrhage, or intraparenchymal hemorrhage.	B

continued

TABLE B-2b Continued

Author	Study Type	Subjects	Exposure
Yuan et al., 2001	Cohort	Men (n=18,244) Aged 45-64 years Shanghai, China No history of cancer Follow-up of 12 years (179,466 person-years) Primary prevention	Seafood and dietary n-3 fatty acid intake

Amount	Results	Conclusion**
Fresh fish = 0.57 g n-3 fatty acids/100 g Salted fish = 0.44 g n-3 fatty acids/100 g Shellfish = 0.36 g n-3 fatty acids/100 g Fish and shellfish categories (g/week): 1 = <50 (<1 serving/week) 2 = 50-<100 (1 serving/week) 3 = 100-<150 (2 servings/week) 4 = 150-<200 (3 servings/week) 5 = ε200 (ε4 servings/week) Quintiles of n-3 fatty acids: (g/week) 1 = <0.27 2 = 0.27-0.43 3 = 0.44-0.72 4 = 0.73-1.09 5 = ε1.10	After controlling for age, total energy intake, level of education, BMI, current smoker at recruitment, average number of cigarettes smoked per day, number of alcoholic drinks consumed per week, history of diabetes, and history of hypertension: There were no significant associations found between fish consumption and risk of stroke mortality; and Those in the 3rd quintile of n-3 fatty acid intake had significantly lower RR of stroke mortality compared to those in the 1st quintile (RR=0.76, 95% CI 0.58-0.98). Those in the 2nd, 4th, and 5th quintiles also had lower RRs of stroke mortality compared to those in the 1st quintile, but they were not significant.	B

continued

TABLE B-2b Continued

Author	Study Type	Subjects	Exposure
Gillum et al., 1996*	Cohort	Men and women (n=5192) Aged 45-74 years White (n=4410) Black (n=782) National Health and Nutrition Examination Survey (NHANES) I No history of stroke at baseline Excluded those with unknown baseline fish consumption, systolic blood pressure, serum cholesterol level, diabetes history, number of cigarettes smoked, BMI, history of heart disease, or educational attainment Average follow-up of 12 years	Seafood
Orencia et al., 1996*	Cohort	Men (n=1847) Aged 40-55 years Employed at least 2 years at the Hawthorne Works of the Western Electric Co. in Chicago, IL 65% first- or second-generation Americans, predominantly of German, Polish, or Bohemian ancestry Chicago Western Electric Study Free of CHD and stroke at baseline Follow-up of 30 years (46,426 person-years)	Seafood

Amount	Results	Conclusion**
Categories of fish consumption: 1 = Never 2 = <1 time/week 3 = 1 time/week 4 = >1 time/week	After adjusting for baseline age, smoking, history of diabetes, history of heart disease, education less than high school graduate, systolic blood pressure, serum albumin concentration, serum cholesterol concentration, BMI, alcohol intake, and physical activity: White women aged 45-74 years who ate fish >1 time/week had a significantly lower RR of acute stroke incidence compared to those who never ate fish (RR=0.55, 95% CI 0.32-0.93); Significant RRs were not found when the women were separated and analyzed based on different age groups (45-64 years and 65-74 years) or for White men; and Black men and women who ate any fish had a significantly lower RR of acute stroke incidence (RR=0.51, 95% CI 0.30-0.88) and stroke death (RR=0.26, 95% CI 0.11-0.64) compared to those who never ate fish.	B
Categories of fish consumption: 1 = None 2 = 1-17 g/day 3 = 18-34 g/day 4 = ε35 g/day	After adjusting for age, systolic blood pressure, cigarette smoking, serum cholesterol, diabetes, ECG abnormalities, table salt use, alcohol intake, iron, thiamine, riboflavin, niacin, vitamin C, beta-carotene, retinol, total energy, polyunsaturated fatty acids, carbohydrates, and total protein, there were no significant associations found between fish consumption and risk of fatal and nonfatal stroke.	N

continued

TABLE B-2b Continued

Author	Study Type	Subjects	Exposure
Morris et al., 1995*	Cohort	Men (n=21,185) Aged 40-84 years US physicians Physicians' Health Study No history of MI, stroke, transient ischemic attacks, cancer, liver or renal disease, peptic ulcer, gout, current use of aspirin, other platelet-active drugs, or nonsteroidal anti-inflammatory agents Follow-up of 4 years	Seafood and dietary n-3 fatty acid intake

Amount	Results	Conclusion**
Categories of fish: 1 = Canned tuna 2 = Dark-meat fish (4-6 oz) 3 = Other fish (4-6 oz) 4 = Shrimp, lobster, or scallops	After adjusting for each level of fish consumption, age, aspirin and beta-carotene assignment, smoking, alcohol consumption, obesity, diabetes mellitus, vigorous exercise, parental history of MI before age 60 years, history of hypertension, history of hypercholesterolemia, vitamin supplement use, and saturated fat intake:	B
Categories of fish intake: 1 = <1 meal/week 2 = 1 meal/week 3 = 2-4 meals/week 4 = ε5 meals/week	Those who consumed 1 fish meal/week had a significantly higher RR of total MI (RR=1.5, 95% CI 1.1-2.1) and cardiovascular deaths (RR=2.6, 95% CI 1.4-4.8) compared to those who consume fish <1 meal/week;	
Quintiles of n-3 fatty acids intake (g/week): 1 = <0.5 2 = 0.5-<1.0 3 = 1.0-<1.7 4 = 1.7-<2.3 5 = ε2.3	No other significant RRs of total myocardial infarction, nonfatal myocardial infarction, stroke, cardiovascular deaths, or total cardiovascular events were found based on weekly fish consumption; Those in the 2nd quintile of omega-3 fatty acid intake had a higher RR of total MI than those in the 1st quintile (RR=1.6, 95% CI 1.1-2.4); and No other significant RR of total MI, nonfatal MI, stroke, cardiovascular deaths, or total cardiovascular events were found based on weekly omega-3 fatty acid intake.	

continued

TABLE B-2b Continued

Author	Study Type	Subjects	Exposure
Keli et al., 1994*	Cohort	Men (n=552) Aged 50-69 years Zutphen, Netherlands The Zutphen Study (Dutch contribution to the Seven Countries Study) Free of stroke at baseline Follow-up of 15 years	Seafood
Kromann and Green, 1980	Cohort	Men and women (n=1800) All ages Born in Greenland and/or with Greenlandic mothers in the Upernavik district, northwest Greenland 5-10% persons of other origin Follow-up of 25 years (40,472 person-years)	Diet

Amount	Results	Conclusion**
Categories of fish consumption: Low = δ20 g/day High = >20 g/day	Fish consumption (g/day) was significantly dif - ferent in those who did not suffer from a stroke (18.3±19.8) than those who did (12.8 ±12.3) after 15 years of follow-up ($p < 0.05$). After adjusting for age, average systolic blood pressure 1960-1970, average serum cholesterol 1960-1970, cigarette smoking until 1970, and intake of energy and vegetable protein, alcohol consumption, and prescribed diet in 1970: Those who consumed >20 g/day of fish had a lower, but not statistically significant, HR of stroke incidence than those who ate δ20 g/day of fish (HR=0.49, 95% CI 0.24-1.01); Those who always consumed fish did not have a significantly lower HR of stroke incidence than those who ate fish "not always" (HR=0.71, 95% CI 0.38-1.33).	B
This population is mainly occupied with whaling and sealing, fowling, and to a lesser degree fishing	Summarizes the disease patterns of cancer, "apo - plexy," epilepsy, peptic ulcer, acute myocardial infarction, rheumatic fever, chronic polyarthritis, chronic pyelonephritis, chronic glomerulonephri - tis, diabetes mellitus, psoriasis, psychosis, multiple sclerosis, and thyrotoxicosis.	N
The traditional diet is supplemented with Danish food	The pattern of disease in this study "differs from that of Western Europe, as we have found frequent occurrence of apoplexy and grand mal epilepsy, but rare or nonoccurrence of acute myocardial infarction, diabetes mellitus, thyrotoxicosis, bron - chial asthma, multiple sclerosis and psoriasis."	

continued

TABLE B-2b Continued

Author	Study Type	Subjects	Exposure
Caicoya, 2002*	Case-control	Cases (n=440) = incident cases of stroke Controls (n=473) = no acute stroke, liv - ing in study area at time of study Aged 40-85 years Asturias, Spain (a northern region)	Seafood and dietary n-3 fatty acid intake
Jamrozik et al., 1994	Case-control	Cases (n=501) = stroke, drawn from the register of acute cerebrovascular events compiled as part of the Perth Community Stroke Study (PCSS) Controls (n=931) = drawn from electoral rolls for the study area of the PCSS Men and women Perth, Western Australia	Seafood

Amount	Results	Conclusion**
Categories of fish consumption (based on the 20th, 50th, and 80th percentiles): 1 = Noneaters, eaters of δ11.2 g/day 2 = 11.3 g/day < x < 28.7 g/day 3 = 28.8 g/day δ x < 46.5 g/day 4 = ε46.5 g/day Categories of n-3 fatty acid intake: 20th percentile = 115 mg/day 50th percentile = 328 mg/day 80th percentile = 660 mg/day	After adjusting for hypertension, alcohol intake, atrial fibrillation, and peripheral artery disease: Those who ate 1-22.5 g of fish/day had a significantly lower OR of stroke compared to those who never ate fish (OR=0.30, 95% CI 0.12-0.78). No significant ORs for stroke were found for those who consumed 23-45, 46-90, or 91-250 g of fish/day; and Those who ate >46.5 g of fish/day had a significantly higher OR of cerebral infarction compared to those who never ate fish (OR=1.98, 95% CI 1.08-3.45). No significant ORs for cerebral infarction were found for those who consumed 11.3-28.7 or 28.8-46.5 g of fish/day; and There was no significant association found between intake of n-3 fatty acids (mg/day) and risk of stroke.	B
Consumption of fish >2 times/month	After adjusting for alcohol and tobacco use, history of hypertension, claudication (for first ever stroke), diabetes mellitus (for primary intracerebral hemorrhage), previous stroke or transient ischemic attack, use of reduced-fat or skim milk: Eating fish >2 times/month significantly lowered the odds of a first-ever stroke (OR=0.60, 95% CI 0.36-0.99) and primary intracerebral hemorrhage (OR=0.42, 95% CI 0.19-0.90), compared to not eating fish >2 times/month. No significant ORs were found for all strokes and ischemic stroke based on consuming fish >2 times/month.	B

continued

TABLE B-2b Continued

Author	Study Type	Subjects	Exposure
Skerrett and Hennekens, 2003	Review	Review of observational studies, randomized trials, and biological studies	Seafood or n-3 supplements
Zhang et al., 1999	Ecological	36 countries Data from the World Health Statistics Annual (WHO) and Food Balance Sheets (FAO) Mortality data age-standardized to 45-74 years, and averaged over latest available 3 years	Seafood

*Included in Wang C, Chung M, Balk E, Kupelnick B, DeVine D. 2004. *Effects of Omega-3 Fatty Acids on Cardiovascular Disease. Evidence Report/Technology Assessment No. 113 (Prepared by the Tufts-New England Medical Center Evidence-based Practice Center, Boston, MA under contract no. 290-02-0023). AHRQ Publication No. 04-E009-1.* Rockville, MD: Agency for Healthcare Research and Quality.

**N = Evidence of no association or no clear association; B = Evidence of a benefit.

Amount	Results	Conclusion**
	"Ecologic/cross-sectional and case-control studies have generally shown an inverse association be - tween consumption of fish and fish oils and stroke risk. Results from five prospective studies have been less consistent, with one showing no associa - tion, one showing a possible inverse association, and three demonstrating a significantly inverse association."	B
	"Consumption of fish several times per week reduces the risk of thrombotic stroke but does not increase the risk of hemorrhagic stroke."	
	"Fish consumption was independently, signifi - cantly, and inversely associated with mortality from all causes, ischemic heart disease, and stroke in both sexes." The statistics for these associations are $p<0.001$, $0.01<p<0.001$, and $0.05<p<0.001$, respectively.	B

TABLE B-2c Studies on Lipid Profile

Author	Study Type	Subjects	Exposure
Dunstan et al., 2003	Randomized Controlled Trial	Women (n=83) Booked for delivery at St. John of God Hospital, Subiaco, Western Australia Atopic pregnancy Allergic women No smoking, other medical problems, complicated pregnancies, preterm delivery, seafood allergy; normal diet intake did not exceed two meals of fish per week From 20 weeks of pregnancy to delivery	n-3 supplement
Christensen et al., 1999	Randomized Controlled Trial	Men (n=35) Women (n=25) Medical staff, bank employees, and students at institutions in Aalborg, Denmark No medications, no known diseases Follow-up of 12 weeks	n-3 supplement

Amount	Results	Conclusion**
Fish oil group: 1.0 g fish oil/capsule, 4 capsules/day 3.7 g n-3 PUFA/capsule (56% DHA, 27.7% EPA) Placebo group: 1 g olive oil/capsule, 4 capsules/day (66.6% n-9 oleic acid, <1% n-3 PUFA)	"Levels of n-6 PUFA AA were significantly lower in the fish oil group (15.02±1.44%, $p<0.001$), compared with the placebo group (17.45 ±1.17%). There was no difference in the levels of oleic acid between the groups." "Interleukin-13 levels were significantly lower (geometric mean 9.61, 95% CI 5.46-16.93, p=0.025) in neonates whose mothers received fish-oil supplements in pregnancy compared to the placebo group (geometric mean 26.32, 95% CI 13.44-51.55)." "There were no significant differences in the frequency of lymphocyte subsets between the two groups with respect to total T cells, T helper cells, T suppressor cells, NK cells, and B cells."	B
High n-3 group: 10 capsules 6.6 g/day n-3 PUFA (3 g EPA/2.9 g DHA) Low n-3 group: 3 capsules n-3, 7 capsules of olive oil 2 g/day n-3 PUFA 0.9 g EPA/0.8 g DHA Placebo group: 10 capsules Olive oil	n-3 PUFA in granulocytes (both for EPA and DHA) and in platelets (both for EPA and DHA) were significantly higher after supplementation, compared to before supplementation, for those in the high n-3 group and the low n-3 group ($p<0.01$). Plasma triacylglycerols were significantly lower after supplementation, compared to before supplementation, for those in the high n-3 group ($p<0.01$) and the low n-3 group ($p<0.05$). The changes in DHA in granulocytes and plasma triacylglyercols after supplementation were significantly higher in the high n-3 group compared to the placebo group ($p<0.05$). The changes in EPA in granulocytes and EPA and DHA in platelets were significantly higher in the high n-3 group than in the low n-3 group and the placebo group ($p<0.05$).	B

continued

TABLE B-2c Continued

Author	Study Type	Subjects	Exposure
Vericel et al., 1999	Randomized Controlled Trial	Men and women (n=20) Aged 70-83 years France Diastolic blood pressure <95 mmHg and systolic blood pressure <180 mmHg No metabolic, malignant, or degenerative diseases Follow-up of 42 days	n-3 supplement
Leng et al., 1998*	Randomized Controlled Trial	Men and women (n=120) Mean age about 66 years Edinburgh, UK Intermittent claudication on the Edinburgh Claudication Questionnaire An ankle brachial pressure index δ0.9 in at least one limb No clinical evidence of critical ischemia; unstable angina or a MI within the previous 3 months; severe intercurrent illnesses including severe liver disorders, malignancy, or epilepsy; concurrent treatment with anticoagulants, other oils, lithium, or phemothiazines; pregnant or actively trying to conceive; already participating in a clinical trial Follow-up of 2 years	n-3 supplement

Amount	Results	Conclusion**
RO-PUFA treatment capsule: 600 mg oil = 150 mg DHA, 30 mg EPA, 1900 ppm alpha-tocopherol	"The composition of platelet total phospholipids was not affected by the low supplementation of RO-PUFA or sunflower oil." "Neither the GSH-Px activities nor the enzyme levels were affected by any supplement of oil."	N
Control capsule: 600 mg sunflower oil and 600 ppm alpha-tocopherol	Compared to baseline, RO-PUFA significantly increased platelet phosphatidylethanolamine DHA (2.7±0.2 mol% to 3.4±0.1 mol%, $p<0.001$).	
Polyunsaturated fatty acids group: 280 mg GLA, 45 mg EPA/capsule 2 capsules twice/day for first 2 weeks, 3 capsules twice daily thereafter	Among completers, VLDL was significantly higher in the polyunsaturated fatty acids group at 6 months ($p\delta 0.05$) and HDL was significantly higher at 24 months ($p\delta 0.01$) compared to the placebo group. At baseline, hematocrit (%) and fibrin D-dimer (ng/ml) were significantly lower in the polyunsaturated fatty acids group compared to the placebo group ($p\delta 0.05$).	B
Placebo group: 500 mg sunflower oil 2 capsules twice/day for first 2 weeks, 3 capsules twice daily thereafter	At 6 months, hematocrit (%) was significantly higher in the polyunsaturated fatty acids group compared to the placebo group ($p\ \delta 0.01$). There were no significant differences in hemostatis factors at 24 months between the two groups.	

continued

TABLE B-2c Continued

Author	Study Type	Subjects	Exposure
Luo et al., 1998*	Randomized Controlled Trial (crossover)	Men (n=10) Mean age of 54 years Patients of the Department of Diabetes outpatient clinic (diabetics) Type II diabetes, a fasting plasma glucose of 7.84-14.0 mmol/L, HbA1c <10.5%, plasma triacylglycerol of 1.72-4.6 mmol/L No abnormal renal, hepatic, and thyroid functions; gastrointestinal disorders Follow-up of 2 months while on each supplement	n-3 supplement

Amount	Results	Conclusion**
Fish oil group: 6 g fish oil 30% n-3 fatty acids; 18% EPA, 12% DHA 2 capsules 3 times/ day Sunflower oil group: 6 g sunflower oil 65% n-6 fatty acids; 0.2% n-3 fatty acids 2 capsules 3 times/ day Recommended to consume 55% of calories as carbo-hydrates, 15% as protein, 30% as fat	There were no significant differences in fasting plasma glucose, insulin, or HbA1c between the two groups. After 2 months of sunflower oil and fish oil treat-ments, the fish oil treatment significantly lowered triacylglycerols and lipoprotein(a) compared to the the sunflower oil treatment ($p<0.05$ and $p<0.02$, respectively). There were no other significant dif-ferences between the two treatments in the other fasting circulating lipid and lipoprotein concentra-tions measured.	B

continued

TABLE B-2c Continued

Author	Study Type	Subjects	Exposure
Dunstan et al., 1997*	Randomized Controlled Trial	Men (n=40) Women (n=15) Aged 30-65 years Perth, Australia With treated noninsulin-dependent diabetes mellitus Nonsmokers, not taking fish-oil supplements or eating >1 fish meal/week, sedentary for the previous 6 months Excluded if taking insulin or medication for lipid disorders; drinking >30 ml alcohol/day; had a previous history or evidence of heart, liver, or renal disease; neuropathy; retinopathy; or had asthma or any orthopedic disorder that precluded exercise participation Follow-up of 8 weeks	Diet (includes seafood) and exercise

Amount	Results	Conclusion**
Group 1: Low-fat diet (δ30% energy from fat) + moderate exercise (55-65% of Vo_2max)	After adjusting for baseline age, sex, and change in body weight: Relative to no fish and light exercise, fish and moderate exercise (Group 3) significantly lowered serum triglycerides (−1.21±0.28; p=0.0001) and significantly raised HDL_2 (0.08±0.03, p=0.02);	B
Group 2: Low-fat diet (δ30% energy from fat) + light exercise (heart rate <100 bpm)	Relative to no fish and light exercise, fish and light exercise (Group 4) significantly lowered serum triglycerides (−1.22±0.28; p=0.0001) and significantly raised HDL_2 (0.08±0.03, p=0.02); and	
Group 3: Low-fat diet with the inclusion of 1 fish meal daily (3.6 g n-3/day) + moderate exercise (55-65% of Vo_2max)	Relative to no fish and light exercise, no fish and moderate exercise (Group 1) significantly lowered serum triglycerides (−0.68±0.29; p=0.03).	
Group 4: Low-fat diet with the inclusion of 1 fish meal daily (3.6 g n-3/day) + light exercise (heart rate <100 bpm)		

continued

TABLE B-2c Continued

Author	Study Type	Subjects	Exposure
Schaefer et al., 1996*	Randomized Controlled Trial	Men and women (n=22) Mean age of 63 (all >40 years, all women postmenopausal) Plasma LDL-cholesterol within the 10th and 90th percentile for their age and sex No medication known to affect plasma lipoprotein cencentrations; no endocrine, liver, or kidney disease Nonsmokers, did not consume alcohol regularly Follow-up of 24 weeks National Cholesterol Education Program (NCEP) Step 2 diet	Seafood

Amount	Results	Conclusion**
Baseline diet: 14.1±2.2 % energy from saturated fat 14.5±1.0 % energy from monounsaturated fat 4.1±0.2 % energy from LA 0.7±0.2 % energy from ALA <0.01 % energy from AA, EPA, DHA each High-fish diet: 4.5±0.7 % energy from saturated fat 11.6±1.4 % energy from monounsaturated fat 7.0±0.4 % energy from LA 1.9±0.6 % energy from ALA 0.1±0.1 % energy from AA 0.2±0.1 % energy from EPA 0.5±0.2 % energy from DHA Low-fish diet: 4.0±0.4 % energy from saturated fat 10.8±0.9 % energy from monounsaturated fat 7.1±0.8 % energy from LA 2.0±0.2 % energy from ALA <0.02 % energy from AA <0.02 % energy from EPA 0.1±0.1 % energy from DHA	Those on the high-fish diet significantly lowered their total cholesterol, LDL-C, HDL-C, apolipoprotein B, apolipoprotein A-I ($p < 0.0001$), and postprandial tricylglycerols ($p < 0.05$). There were no significant changes found for VLDL-C, TC:HDL-C, (triacylglycerols, lipoprotein(a), or LDL particle score. Those on the low-fish diet significantly lowered their total cholesterol, LDL-C, HDL-C, apolipoprotein B, apolipoprotein A-I ($p < 0.0001$), and significantly increased their LDL particle score ($p < 0.05$). There were no significant changes found for VLDL-C, TC:HDL-C, triacylglycerols, postprandial triacylglycerols, and lipoprotein(a).	B

continued

TABLE B-2c Continued

Author	Study Type	Subjects	Exposure
Eritsland et al., 1995*	Randomized Controlled Trial	Men (n=523) Women (n=78) Aged 36-81 years Oslo, Norway With stenosing coronary artery disease Referred for coronary artery bypass grafting Follow-up of 6 months Reference group (for serum Lp(a)): Men (n=79) Women (n=20) Aged 25-81 years Apparently healthy Current or retired employees attending a regular health check-up	n-3 supplement
Sacks et al., 1995	Randomized Controlled Trial	Men and women (n=59) Aged 30-75 years Boston, MA Had narrowing of ε30% lumen diameter of a major coronary artery, a total cholesterol concentration <250 mg/dL, and triglyceride level <350 mg/dL No congestive heart failure, liver, renal, or serious gastrointestinal disease, insulin-dependent diabetes mellitus, current cigarette smoking, or alcohol intake >14 drinks/week Follow-up of 2.4 years	n-3 supplement

Amount	Results	Conclusion**
n-3 PUFA group: 4 capsules/day Each capsule = 1 g n-3 PUFA (51% EPA, 32% DHA) + 3.7 IU alpha-tocopherol	Serum EPA, DHA, and total n-3 concentrations significantly increased in the n-3 PUFA group between baseline and the 6-month assessment ($p < 0.001$). The changes in serum EPA, DHA, and total n-3 concentrations from baseline to the 6-month assessment were also significantly higher in the n-3 PUFA group compared to the control group ($p < 0.001$). Among those who had a baseline Lp(a) of ε20 mg/dL, the change in serum Lp(a) levels from baseline to the 6-month assessment was significantly different in the n-3 PUFA group (29.7 mg/dL to 28.7 mg/dL) than in the control group (30.3 mg/dL to 30.8 mg/dL) ($p=0.023$). There were no significant differences in the change of serum Lp(a) found between the two groups among those who had a baseline Lp(a) of <20 mg/dL.	B
Fish oil group: 12 capsules/day 500 mg n-3 fatty acids/capsule (240 mg EPA, 160 mg DHA, 100 mg mostly DPA) 6 g of n-3 fatty acids/day	From baseline to follow-up, there was a significant increase in body weight, LDL-C, apolipoprotein B, and Lp(a), and a significant decrease in triglycerides among those in the fish oil group ($p < 0.01$; $p < 0.05$ for lipoprotein Lp(a)). From baseline to follow-up there was a significant increase in body weight ($p < 0.01$), cholesterol ($p < 0.05$), and apolipoprotein B ($p < 0.01$) among those in the control group.	B
Control group: 12 capsules of olive oil/day	The change in triglycerides from baseline to follow-up was significantly different among the fish oil group (-28 ± 53 mg/dL) and the control group (6 ± 35 mg/dL) ($p < 0.01$). After 2.4 years of supplementation, the fish oil group had significantly higher EPA, DPA, DHA, and EPA+DPA+DHA ($p < 0.0001$) and significantly lower palmitic acid ($p=0.048$), oleic acid ($p=0.0009$), and arachidonic acid ($p=0.001$) in the adipose tissue compared to the control group.	

continued

TABLE B-2c Continued

Author	Study Type	Subjects	Exposure
Mori et al., 1994*	Randomized Controlled Trial	Men (n=120) Aged 30-60 years Perth, Australia Eating not more than one fish meal/week or drinking more than an average of 30 mL alcohol/day (3 standard drinks) With high-normal blood pressure and elevated serum cholesterol No history of unstable heart, renal, or liver disease, hypercholesterolemia, asthma, or any major allergies Follow-up of 12 weeks	Seafood and n-3 supplements

Amount	Results	Conclusion**
Seven dietary groups: 40% total energy from fat and: 1 = placebo 2 = fish (1 fish meal/day) 3 = fish-oil capsules (0.8 g/day DHA, 2.6 g n-3/day) 4 = fish (1 fish meal/day) and fish-oil capsules (0.8 g/day DHA, 2.6 g n-3/day) 5 = twice the dosage of fish-oil capsules (1.6 g/day DHA, 5.2 g n-3/day) 30% total energy from fat and: 6 = control group 7 = fish (1 fish meal/day) Fish meals included: Greenland turbot fillets (160 g/day) = 1.5 g/day DHA, 3.5 g/day total n-3 fatty acids Canned sardines (95 g/day) = 1.7 g/day DHA, 4.1 g/day total n-3 fatty acids Tuna (90 g/day) = 1.3 g/day DHA, 3.2 g/day total n-3 fatty acids Salmon (90 g/day) = 2.4 g/day DHA, 3.8 g/day total n-3 fatty acids	Among those in Groups 1-5, there were significant differences between the groups in the change in percentage of daily fat intake from polyunsaturated fatty acids (change (%) = −4.5, 0.9, −7.1, 0.9, and −1.9, respectively; $p<0.001$). Among those in Groups 6-7, there were significant differences between the groups in the change in percentage of daily fat intake from polyunsaturated fatty acids (change (%) = 13.0 and 18.9, respec - tively; $p<0.01$). Among those in Groups 1-5, there were significant differences between the groups in regards to the change in cholesterol (change (mg/d) = 124.3, −33.8, 188.3, 103.4, and 58.7, respectively; $p<0.01$). There were no significant changes in % of energy from total fat, % of daily fat from monounsaturated fatty acids or saturated fatty acids, total carbohy - drate, total protein, or fiber intake.	B

continued

TABLE B-2c Continued

Author	Study Type	Subjects	Exposure
Vandongen et al., 1993	Randomized Controlled Trial	Men (n=120) Aged 30-60 years Perth, Australia BMI <33 kg/m^2, SBP 130-159 mmHg, DBP 80-99 mmHG, serum cholesterol 5.2-6.9 mmol/L, nonsmoking, not tak - ing any medication, no significant illness or allergic disorder Eating δ1 fish meal and drinking <210 mL alcohol/week Follow-up of 12 weeks	Seafood and n-3 supplements

Amount	Results	Conclusion**
Seven dietary groups: 40% total energy from fat and: 1 = placebo 2 = fish (1 fish meal/day) 3 = fish-oil capsules (1.3 g n-3/day) 4 = fish (1 fish meal/day) and fish-oil capsules (1.3 g n-3/day) 5 = twice the dosage of fish-oil capsules (2.6 g n-3/day) 30% total energy from fat and: 6 = control group 7 = fish (1 fish meal/day) Fish meals included: Greenland turbot fillets (160 g/day) 3.5 g/day total n-3 fatty acids Canned sardines (95 g/day) 4.1 g/day total n-3 fatty acids Tuna (90 g/day) 3.2 g/day total n-3 fatty acids Salmon (90 g/day) 3.8 g/day total n-3 fatty acids	A significant group effect was found for the change in heart rate ($p<0.01$ for supine; $p = 0.06$ for erect) from baseline to end of intervention. No significant differences were found between groups in SBP, DBP, weight, 24-hour urine potassium levels, sodium, blood glucose, or blood insulin from baseline to end of intervention.	B

continued

TABLE B-2c Continued

Author	Study Type	Subjects	Exposure
Cobiac et al., 1991*	Randomized Controlled Trial	Men (n=31) Aged 30-60 years Adelaide, South Australia Mildly hyperlipidemic and normotensive No history of heart disease, hypertension, bleeding disorders, liver or renal disorders, gout, diabetes, recent cerebrovascular accident, or obesity No steroids, nonsteroidal anti-inflammatory drugs, aspirin, beta-blockers, allopurinol, or cardiac glycosides No excessive alcohol intake (>40 g/day) or smoked >20 cigarettes/day Follow-up of 8 weeks	Seafood and n-3 supplementation
Hanninen et al., 1989*	Randomized Controlled Trial	Men (n=100) Mean age of 23.5 years Kuopio, Finland Healthy students Follow-up of 12 weeks	Seafood

Amount	Results	Conclusion**
Fish treatment: 1 kg (raw) Atlantic salmon + 150 g sardines in sild oil per week 4.5 g EPA+DHA/day Fish-oil treatment: 105 g MaxEPA/week 4.6 g EPA+DHA/day Continued with meats as during baseline Control diet: Continuation of baseline diet	After the fish treatment (compared to baseline values), cholesterol, triglycerides, VLDL-C, LDL-C, VLDL triglycerides, Apo A-I, and Apo A-II were significantly lower and HDL, Apo A-I:Apo A-II, and HDL-C:Apo A-I were significantly higher ($p < 0.05$). After the fish-oil treatment (compared to baseline values), triglycerides, VLDL-C, VLDL triglycerides, Apo A-I, Apo-AII, and Apo A-I:Apo B were signifi - cantly lower, and HDL-C, Apo A-I:Apo A-II, and HDL-C:Apo A-I were significantly higher ($p < 0.05$). After the control treatment (compared to baseline values), lipids, LDL-C, and Apo A-I were signifi - cantly lower and HDL-C:Apo A-I was significantly higher ($p < 0.05$). The changes in triglycerides, VLDL-C, VLDL triglycerides, and HDL-C:Apo A-I in the fish and fish-oil groups were significantly greater than the changes in the control group ($p < 0.05$, $p = 0.002$ for HDL-C:Apo A-I); the change in HDL-C was significantly greater in the fish-oil group than in the control group ($p < 0.05$). The changes in fibrinogen, thromboxane, and bleed - ing time after treatment were significantly different in the fish group compared to the control group ($p < 0.05$).	B
Fish meal groups: 0.9, 1.5, 2.3, or 3.8 fish meals/week Controls: 1 fish meal/2 weeks Meals = Finnish freshwater fish (rainbow trout, vendace, and perch) and brack - ish water fish (Baltic herring) Portion size = 150 g	Those who ate 3.8 fish meals/week lowered their serum triglycerides and apolipoprotein B signifi - cantly ($p < 0.02$ and $p < 0.05$, respectively) after eating the fish diet for 12 weeks; there were no significant changes after 12 weeks for those who ate 0.9, 1.5, and 2.3 fish meals/week. There were no significant changes in serum cho - lesterol, serum apolipoprotein A-I, hemoglobin, thrombocytes, vitamin E, or vitamin A after eating the fish diets for 12 weeks.	B

continued

TABLE B-2c Continued

Author	Study Type	Subjects	Exposure
Dewailly et al., 2001	Cohort	Men and women (n=426) Aged 18-74 years Permanent residents of Nunavik, Canada Inuit Excluded households of only non-Inuit persons, persons not related to an Inuit, and institutionalized persons	Plasma phospho-lipid com-position; seafood; diet

*Included in Balk E, Chung M, Lichtenstein A, Chew P, Kupelnick B, Lawrence A, DeVine D, Lau J. 2004. *Effects of Omega-ƒ Fatty Acids on Cardioƒascular Risk Factors and Intermediate Markers of Cardioƒascular Disease. Summary, Eƒidence Report/Technology Assessment No. ƒƒ. (Prepared by the Tufts-New England Medical Center Eƒidence-based Practice Center, Boston, MA). AhRQ Publication No. 0ƒ-E0ƒ0-ƒ.* Rockville, MD: Agency for Healthcare Research and Quality.

**B = Evidence of a benefit; N = Evidence of no association or no clear association.

Amount	Results	Conclusion**
Plasma phospholipids = relative percentages of total fatty acids by weight Fish and marine mammal intake from 24-hour recalls Consumption of traditional and market food stuffs from a food frequency questionnaire	After adjusting for age, sex, waist girth, smoking status, and alcohol intake: EPA, DHA, EPA+DHA, EPA:AA, and n-3:n-6 are positively associated with total cholesterol (p=0.0001); EPA (p=0.005), DHA (p=0.0003), EPA+DHA (p=0.0007), EPA:AA (p=0.002), and n-3:n-6 (p=0.003) are positively associated with LDL; EPA (p=p=0.0001), DHA (p=0.004), EPA+DHA (p=0.0001), EPA:AA (p=0.0001), and n-3:n-6 (p=0.0001) are positively associated with HDL; EPA (p=0.04) and EPA:AA (p=0.05) are negatively associated with total cholesterol:HDL; EPA (p=0.0001), EPA+DHA (p=0.0003), EPA:AA (p=0.0002), and n-3:n-6 (p=0.001) are negatively associated with triacylglycerols; and EPA (p=0.02), DHA (p=0.01), EPA+DHA (p=0.008), EPA:AA (p=0.02), and n-3:n-6 (p=0.008) are positively associated with glucose.	N

TABLE B-2d Studies on Blood Pressure

Author	Study Type	Subjects	Exposure
Hooper et al., 2005	Cochrane Review	7 studies (2743 participants) After 6 months of supplementation	n-3 supplement
Geleijnse et al., 2002*	Meta-analysis	36 RCTs (22 with double-blinded design) Adult study populations (mean age ε18 years) Published after 1966 No sick/hospitalized populations, including renal and diabetic patients Mean trial duration of 11.7 weeks (range = 3-52 weeks)	n-3 supplement

Amount	Results	Conclusion*
	"Neither [systolic or diastolic blood pressure] were significantly affected by omega-3 supplementation" (SBP mean difference = 1.03 mmHg, 95% CI −3.30 to 1.25, p=0.18; DBP mean difference = −0.23 mmHg, 95% CI 1.10-0.64, p=0.92).	N
Doses of fish oil: <1.0 g/day in 1 trial 1.0-1.9 g/day in 5 trials 2.0-2.9 g/day in 4 trials 3.0-15.0 g/day in 26 trials mean dose = 3.7 g/day	In the univariate analysis: Based on all trials, fish oil decreased SBP and DBP significantly more among those >45 years of age compared to those δ45 years of age (p=0.023 for SBP and p=0.020 for DBP) and in those with hypertension compared to those without hypertension (p=0.008 for SBP and p=0.041 for DBP). Fish oil also decreased SBP and DBP more in populations with males and females compared to those with only males and among those with a BMI >26.8kg/m^2 compared to those with BMI δ26.8 kg/m^2, but the differences were not significant; and Based on double-blinded trials, fish oil decreased SBP and DBP significantly more among those with hypertension compared to those without hypertension (p=0.005 for SBP and p=0.010 for DBP). Fish oil also decreased SBP and DBP more among those >45 years of age compared to those δ45 years of age; in populations with males and females compared to those with only males, and among those with a BMI >26.8kg/m^2 compared to those with BMI δ26.8 kg/m^2, but the differences were not significant. After adjusting for age, percent males, baseline BP, study design, and fish oil dose: Fish oil decreased SBP and DBP more among those >45 years of age compared to those δ45 years of age, in populations with males and females compared to those with only males, in those with hypertension compared to those without hypertension, and among those with a BMI >26.8kg/m^2 compared to those with BMI δ26.8 kg/m^2, but the differences were not significant.	N

continued

TABLE B-2d Continued

Author	Study Type	Subjects	Exposure
Ness et al., 1999	Randomized Controlled Trial	Men (n=2033) Aged <70 years From 21 hospitals in South Wales and the south west of England Diet and Reinfarction Trial (DART) Suffered from recent MI Excluded if they already intended to eat one of the study diets, if they had serious illnesses (e.g., diabetes, cancer, or renal function), if they were being considered for cardiac surgery, if they were participating in a local cohort study, if they planned to live outside the study area, if they were averse to one of the proposed diets Follow-up of 2 years	Dietary advice
Vericel et al., 1999	Randomized Controlled Trial	Men and women (n=20) Aged 70-83 years France Diastolic blood pressure <95 mmHg and systolic blood pressure <180 mmHg No metabolic, malignant, or degenerative diseases Follow-up of 42 days	n-3 supplement
Leng et al., 1998*	Randomized Controlled Trial	Men and women (n=120) Mean age about 66 years Edinburgh Intermittent claudication on the Edinburgh Claudication Questionnaire An ankle brachial pressure index δ0.9 in at least one limb No clinical evidence of critical ischemia; unstable angina or a myocardial infarction within the previous 3 months; severe intercurrent illnesses including severe liver disorders, malignancy, or epilepsy; concurrent treatment with anticoagulants, other oils, lithium, or phemothiazines; pregnant or actively trying to conceive; already participating in a clinical trial Follow-up of 2 years	n-3 supplement

Amount	Results	Conclusion*
Eight dietary regimes: 1 = Fat advice 2 = Fish advice 3 = Fiber advice 4 = Fat and fish advice 5 = Fat and fiber advice 6 = Fish and fiber advice 7 = Fat, fish, and fiber advice 8 = No advice	After adjusting for 5-year age group and BP at baseline: At 6 months, those who received fish advice had lower SBP and DBP than those who did not receive fish advice (difference in SBP = −0.61, 95% CI −2.15 to 0.92 and difference in DBP = −0.50, 95% CI −1.47 to 0.46), but the differences were not significant; and At 2 years, those who received fish advice had higher SBP and DBP than those who did not receive fish advice (difference in SBP = 0.40, 95% CI −1.33 to 2.13 and difference in DBP = 0.19, 95% CI −0.88 to 1.26), but the differences were not significant.	B
RO-PUFA treatment capsule: 600 mg oil = 150 mg DHA, 30 mg EPA, 1900 ppm alpha-tocopherol Control capsule: 600 mg sunflower oil and 600 ppm alpha-tocopherol	Compared to baseline, RO-PUFA significantly lowered systolic blood pressure (145.5 ±5.1 mmHg to 131.5±4.5 mmHg, $p<0.001$). There was no significant change in diastolic blood pressure.	B
Polyunsaturated fatty acids group: 280 mg GLA, 45 mg EPA/capsule 2 capsules twice/day for first 2 weeks, 3 capsules twice/day thereafter Placebo group: 500 mg sunflower oil 2 capsules twice/day for first 2 weeks, 3 capsules twice/day thereafter	There were no significant differences in systolic blood pressure or diastolic blood pressure between the two groups at baseline or at 6 months. At 24 months systolic blood pressure was significantly lower in the polyunsaturated fatty acids group compared to the placebo group (150.1 ±3.5 mmHg vs. 161.8±3.1 mmHg, $p\delta0.05$).	B

continued

TABLE B-2d Continued

Author	Study Type	Subjects	Exposure
Vandongen et al., 1993	Randomized Controlled Trial	Men (n=120) Aged 30-60 years Perth, Australia BMI <33 kg/m^2, SBP 130-159 mmHg, DBP 80-99 mmHG, serum cholesterol 5.2-6.9 mmol/L, nonsmoking, not tak - ing any medication, no significant illness or allergic disorder Eating δ1 fish meal and drinking <210 mL alcohol/week Follow-up of 12 weeks	Seafood and n-3 supplements

Amount	Results	Conclusion*
Seven dietary groups: 40% total energy from fat and: 1 = placebo 2 = fish (1 fish meal/day) 3 = fish-oil capsules (1.3 g n-3/day) 4 = fish (1 fish meal/day) and fish-oil capsules (1.3 g n-3/day) 5 = twice the dosage of fish-oil capsules (2.6 g n-3/day) 30% total energy from fat and: 6 = control group 7 = fish (1 fish meal/day) Fish meals included: Greenland turbot fillets (H160 g/day) H3.5 g/day total n-3 fatty acids Canned sardines (H95 g/day) H4.1 g/day total n-3 fatty acids Tuna (H90 g/day) H3.2 g/day total n-3 fatty acids Salmon (H90 g/day) H3.8 g/day total n-3 fatty acids	There was a significant difference in change in heart rate (bpm) from baseline until the end of the intervention between the groups ($p < 0.01$). Heart rate went down in Groups 2, 3, 4, 5, and 7 and heart rate went up in Groups 1 and 6.	B

continued

TABLE B-2d Continued

Author	Study Type	Subjects	Exposure
Cobiac et al., 1991*	Randomized Controlled Trial	Men (n=31) Aged 30-60 years Adelaide, South Australia Mildly hyperlipidemic and normotensive No history of heart disease, hypertension, bleeding disorders, liver or renal disorders, gout, diabetes, recent cerebrovascular accident, or obesity No steroids, nonsteroidal anti-inflammatory drugs, aspirin, beta-blockers, allopurinol, or cardiac glycosides No excessive alcohol intake (>40 g/day) or smoked >20 cigarettes/day Follow-up of 8 weeks	Seafood and n-3 supplementation
Dewailly et al., 2001	Cohort	Men and women (n=426) Aged 18-74 years Permanent residents of Nunavik, Canada Inuit Excluded households of only non-Inuit persons, persons not related to an Inuit, and institutionalized persons	Plasma phospholipid composition; seafood; diet

Amount	Results	Conclusion*
Fish treatment: 1 kg (raw) Atlantic salmon + 150 g sardines in sild oil per week 4.5 g EPA+DHA/day Fish-oil treatment: 105 g MaxEPA/week 4.6 g EPA+DHA/day Continued with meats as during baseline Control diet: Continuation of baseline diet	After fish treatment, compared to baseline values, systolic and diastolic blood pressure were significantly lower ($p<0.05$). After the fish-oil treatment, compared to baseline values, systolic blood pressure was significantly lower ($p<0.05$). After the control treatment, compared to baseline values, diastolic blood pressure was significantly lower ($p<0.05$). There were no significant differences between the changes in the three treatment groups.	B
Plasma phospholipids = relative percentages of total fatty acids by weight Fish and marine mammal intake from 24-hour recalls Consumption of traditional and market food stuffs from a food frequency questionnaire	After adjusting for age, sex, waist girth, smoking status, and alcohol intake, no significant associations were found between EPA, DHA, EPA+DHA, EPA:AA or n-3:n-6 and systolic blood pressure or diastolic blood pressure.	N

continued

TABLE B-2d Continued

Author	Study Type	Subjects	Exposure
Appleby et al., 2002	Cross-sectional	Men (n=2351) Women (n=8653) Aged 20-78 years UK European Prospective Investigation into Cancer and Nutrition (EPIC)—Oxford Cohort Free of cancer at baseline	Diet

*Included in Balk E, Chung M, Lichtenstein A, Chew P, Kupelnick B, Lawrence A, DeVine D, Lau J. 2004. *Effects of Omega-3 Fatty Acids on Cardiovascular Risk Factors and Intermediate Markers of Cardiovascular Disease. Summary, Evidence Report/Technology Assessment No. 113. (Prepared by the Tufts-New England Medical Center Evidence-based Practice Center, Boston, MA). AHRQ Publication No. 04-E010-3.* Rockville, MD: Agency for Healthcare Research and Quality.

Amount	Results	Conclusion*
Four diet groups: Meat eaters Fish eaters = ate fish but no meat Vegetarians = ate neither meat nor fish but did eat dairy products and/or eggs Vegans = did not eat any meat, fish, eggs, or dairy products	After adjusting for age, there were significant differences between the diet groups in regards to SBP among men ($p<0.005$), SBP among women ($p<0.005$), DBP among men ($p<0.005$) and DBP among women ($p<0.0001$). After adjusting for age and BMI, the only significant difference in blood pressure was for DBP among women ($p<0.01$). After adjusting for age, BMI, alcohol intake and vigorous exercise (for men), and hormone exposure (for women), the only significant difference in blood pressure was for DBP among women ($p<0.01$). After adjusting for age, BMI, alcohol intake and vigorous exercise (for men), hormone exposure (for women), protein, carbohydrate, total fat, saturated fat and polyunsaturated fat, energy, P/S ratio, and NSP intake, the only significant difference in blood pressure was for DBP among women ($p=0.02$). After adjusting for age, BMI, alcohol intake and vigorous exercise (for men), hormone exposure (for women), protein, carbohydrate, total fat, saturated fat and polyunsaturated fat, energy, P/S ratio, and NSP intake, sodium (from food only), potassium, calcium, and magnesium intakes, the only significant difference in blood pressure was for DBP among women ($p=0.02$). After adjusting for age, the prevalence of self-reported hypertension for meat eaters, fish eaters, vegetarians, and vegans was 15.0%, 9.8%, 9.8%, and 5.8% for men, respectively, and 12.1%, 9.6%, 8.9%, and 7.7% for women, respectively. After adjusting for age and BMI, the prevalence of self-reported hypertension for meat eaters, fish eaters, vegetarians, and vegans was 12.9%, 9.3%, 9.5%, and 6.1% for men, respectively, and 10.6%, 9.7%, 8.7%, and 8.3% for women, respectively.	B

**N = Evidence of no association or no clear association; B = Evidence of a benefit.

TABLE B-2e Studies on Arrhythmia

Author	Study Type	Subjects	Exposure
Leaf et al., 2003	Review	Clinical trials (n=6 analyses) Animal and laboratory studies (for potential mechanisms)	n-3 supplement
Christensen et al., 1999	Randomized Controlled Trial	Men (n=35) Women (n=25) Medical staff, bank employees, and students at institutions in Aalborg, Denmark No medications, no known diseases 12 weeks of follow-up	n-3 supplement
Christensen et al., 1996	Randomized Controlled Trial	Men and women (n=49) Aged δ75 years Aalborg Hospital, Denmark Discharged after MI and ventricular ejection fraction <0.40 No pacemakers or permanent tachyarrhythmias, or serious non-cardiac disease Follow-up of 12 weeks	n-3 supplement

Amount	Results	Conclusion*
	From the randomized controlled trials, "the evidence has been strengthened that fish oil fatty acids can prevent sudden cardiac death in humans, and this may prove to be their major cardiac benefit." From the randomized controlled trials, there were no significant associations found between fish oil fatty acids and the reduction of nonfatal MIs. "If there is a family history of sudden cardiac death, then the supplement should be increased to 1 to 2 g of EPA plus DHA." "These n-3 fatty acids are antiarrhythmis and can prevent sudden cardiac death in humans."	B
High n-3 group: 10 capsules 6.6 g/day n-3 PUFA 3 g EPA/2.9 g DHA Low n-3 group: 3 capsules n-3, 7 capsules of olive oil 2 g/day n-3 PUFA 0.9 g EPA/0.8 g DHA Placebo group: 10 capsules Olive oil	There were no significant differences between the three diet groups in regards to the changes in six heart rate variability indexes from before to after supplementation.	B
n-3 fatty acid group: 5.2 g n-3 PUFA 4.3 g EPA and DHA Placebo group: Olive oil	After n-3 polyunsaturated fatty acid treatment, the mean heart rate variability, defined as standard deviation of all normal RR intervals in 24-hour Holter recording, was significantly higher compared to baseline (124 ms vs. 115 ms, p=0.04). The mean difference in heart rate variability, defined as standard deviation of all normal RR intervals in 24-hour Holter recording, was significantly different after n-3 polyunsaturated fatty acid treatment (mean difference = −8.3, 95% CI −16 to −1) compared to after the control treatment (mean difference = 9.4, 95% CI −2 to 20, p=0.01).	A

continued

TABLE B-2e Continued

Author	Study Type	Subjects	Exposure
Frost and Vestergaard, 2005	Cohort	Men (n=22,528) Women (n=25,421) Aged 50-64 years Born in Denmark, living in the Copenhagen and Aarhus areas No previous cancer diagnosis in the Danish Cancer Registry No hospitalization before baseline with endocrine diseases or cardiovascular diseases other than hypertension Follow-up of 5.7 years (128,131 person-years for men and 147,251 person-years for women)	Seafood
Christensen et al., 1997	Cross-sectional	Men and women (n=52) Aged 48-75 years Discharged after MI from Aalborg Hospital, Denmark Echocardiography performed within the first week after MI Left ventricular ejection fraction δ40% No implanted pacemaker, no permanent tachyarrhythmias, no serious noncardiac disease Using baseline data from Christensen et al., 1996	Platelet fatty acids; seafood

*B = Evidence of a benefit; A = Evidence of an adverse effect; N = Evidence of no association or no clear association.

Amount	Results	Conclusion*
Frequency of fish consumption: Never, <1 time/ month, 1 time/ month, 2-3 times/month, 1 time/week, 2-4 times/week, 5-6 times/week, 1 time/ day, 2-3 times/day, 4-5 times/day, 6-7 times/day, ε8 times/day Quintiles of n-3 PUFA from fish (g/day): Quintile 1 = 0.16±0.08 Quintile 2 = 0.36±0.06 Quintile 3 = 0.52±0.07 Quintile 4 = 0.74±0.10 Quintile 5 = 1.29±0.47	After adjusting for age, sex, height, BMI, smoking, consumption of alcohol, total energy intake, systolic blood pressure, treatment for hypertension, total serum cholesterol, and level of education: Those in Quintile 5 of n-3 PUFA from fish had a significantly higher hazard rate ratio of atrial fibrillation or flutter, when compared to those in Quintile 1 (HRR=1.34, 95% CI 1.02-1.76); and The association between n-3 PUFA from fish and risk of atrial fibrillation or flutter was not significant for any other quintiles when compared to Quintile 1, however there was a positive trend (p=0.006).	N
3 groups of DHA content in platelets: 1 = <2.26% 2 = 2.26-3.14% 3 = >3.14% Fish intake: 1 = 0 times/week 2 = 1 time/week 3 = ε2 times/week	The standard deviation of all normal RR intervals in the entire 24-hour recording was higher in those who ate fish at least 1 time/week (122 ms for those who ate fish 1 time/week and 119 ms for those who ate fish ε2 times/week), compared to those who ate fish 0 times per week (103 ms), but these differences were not significant. The standard deviations of all normal RR intervals in the entire 24-hour recording for those in the first, second, and third tertile of DHA contents in platelets were approximately 98 ms, 116 ms, and 140 ms, respectively.	A

TABLE B-2f Studies on Other Cardiac Indicators

Author	Study Type	Subjects	Exposure
Agren et al., 1997*	Randomized Controlled Trial	Men (n=55) Healthy students Kuopio, Finland Follow-up of 15 weeks	Seafood and n-3 supplementation
Cobiac et al., 1991*	Randomized Controlled Trial	Men (n=31) Aged 30-60 years Adelaide, South Australia Mildly hyperlipidemic and normotensive No history of heart disease, hypertension, bleeding disorders, liver or renal disorders, gout, diabetes, recent cerebrovascular accident, or obesity No steroids, nonsteroidal anti-inflammatory drugs, aspirin, beta-blockers, allopurinol, or cardiac glycosides No excessive alcohol intake (>40 g/day) or who smoked >20 cigarettes/day Follow-up of 8 weeks	Seafood and n-3 supplementation

*Included in Balk E, Chung M, Lichtenstein A, Chew P, Kupelnick B, Lawrence A, DeVine D, Lau J. 2004. *Effects of Omega-3 Fatty Acids on Cardiovascular Risk Factors and Intermediate Markers of Cardiovascular Disease. Summary, Evidence Report/Technology Assessment No. 83. (Prepared by the Tufts-New England Medical Center Evidence-based Practice Center, Boston, MA). AHRQ Publication No. 04-E030-3.* Rockville, MD: Agency for Healthcare Research and Quality.

** N = Evidence of no association or no clear association; B = Evidence of a benefit.

Amount	Results	Conclusion **
Fish-diet group: 4.30±0.50 fish containing meals/week 0.38±0.04 g EPA and 0.67±0.098 g DHA/day Fish-oil group: 4 g/day 1.33 g EPA and 0.95 g DHA/day DHA-oil group: 4 g/day 1.68 g DHA/day	The change in Factor X (% of normal) from baseline to 15 weeks was significantly greater in the fish-diet group compared to the control group ($p < 0.05$). The change in collagen (50 ∝g/ml) from baseline to 15 weeks was significantly greater in the fish-diet group and the fish-oil group when compared to the controls ($p < 0.05$). No other significant associations were found between the diet groups with regards to the change in PT (ratio), APTT (ratio), Factor VII (% of normal), Factor X (% of normal), fibrinogen (g/l), prothrombin fragment 1+2 (nmol/L), tissue factor pathway inhibitor (ng/mL), platelet aggregation (%T), ADP (2.0 ∝mol/L), ADP (5.0 ∝mol/L), and collagen (50 ∝g/L).	N
Fish treatment: 1 kg (raw) Atlantic salmon + 150 g sardines in sild oil per week 4.5 g EPA+DHA/day Fish-oil treatment: 105 g MaxEPA/week 4.6 g EPA+DHA/day Continued with meats as during baseline Control diet: Continuation of baseline diet	The changes in fibrinogen and thromboxane were significantly lower and the change in bleeding time was significantly longer in the fish-diet group compared to the control diet group ($p < 0.05$).	B

TABLE B-2g Studies on Diabetes

Author	Study Type	Subjects	Exposure
Dunstan et al., 1999*	Randomized Controlled Trial	Men and women (n=55) Mean age about 53 years Western Australia Nonsmoking, treated type II diabetes Fasting serum triglyceride >1.8 mmol/L and/or HDL-C <1.0 mmol/L and BMI <36.0 kg/m^2 Follow-up of 8 weeks	Diet (includes seafood) and exercise

Amount	Results	Conclusion**
Group 1: Low-fat diet (δ30% energy from fat) + moderate exercise (55-65% of Vo_2max)	The change in erythrocyte omega-3 fatty acids from baseline to end of intervention were significantly different for both the fish and moderate exercise (Group 3) and the fish and light exercise (Group 4) compared to the controls ($p < 0.05$).	B
Group 2: Low-fat diet (δ30% energy from fat) + light exercise (heart rate <100 bpm)	The change in plasma tPa antigen from baseline to end of intervention were significantly different for the fish and moderate exercise (Group 3), fish and light exercise (Group 4), and no fish and moderate exercise (Group 1) groups compared to the controls ($p<0.05$).	
Group 3: Low-fat diet with the inclusion of 1 fish meal daily (3.6 g n-3/day) + moderate exercise (55-65% of Vo_2max)	The change in erythrocyte omega-6 fatty acids from baseline to end of intervention were significantly different for both the fish and moderate exercise (Group 3) and the fish and light exercise (Group 4) compared to the controls ($p < 0.05$).	
Group 4: Low-fat diet with the inclusion of 1 fish meal daily (3.6 g n-3/day) + light exercise (heart rate <100 bpm)	The change in plasma factor VII from baseline to end of intervention was significantly different for the fish and light exercise group compared to the control group ($p<0.05$). There were no significant differences in change in plasma PAI-1 antigen or change in plasma fibrinogen from baseline to end of intervention for the three other treatment groups compared to the controls.	

continued

TABLE B-2g Continued

Author	Study Type	Subjects	Exposure
Mori et al., 1999*	Randomized Controlled Trial	Men and women (n=63) Aged 40-70 years Royal Perth Hospital, Australia Nonsmoking men and postmenopausal women Overweight, BMI >25, systolic blood pressure 125-180 mmHg, diastolic blood pressure <110 mmHg Receiving antihypertensive treatment for ε3 months No lipid-lowering or antiinflammatory drugs, no more than 1 fish meal/week, drank <175 g alcohol/week Follow-up of 16 weeks	Seafood; diet
Sirtori et al., 1998*	Randomized Controlled Trial	Men and women (n=935) Aged 45-75 for men Aged 55-80 for women Italy (63 clinical groups) Presenting with hyperlipoproteinemias type IIb or IV, associated with at least one further risk factor No severe intercurrent ailments, kidney or renal disease, intestinal malabsorptions, duodenal ulcer nonresponsive to therapy, BMI ε30, history of vascular or nonvascular brain disease, severe hyperlipidemia needing drug treatment, severe hypertension, myocardial infarction in the preceding 3 months, or unstable angina Follow-up of 1 year	n-3 supplement

Amount	Results	Conclusion**
Control group = weight-maintaining diet Fish group = weight-maintaining diet + fish daily (about 3.65 n-3/day) Weight loss group = energy restricted diet (to achieve 5-8 kg weight loss) Fish + weight loss group = energy restricted diet + fish daily	From baseline to end of intervention, the fish + weight loss diet significantly increased plasma phospholipid n-3 fatty acids ($p < 0.0001$) and significantly decreased plasma phospholipid n-6 fatty acids ($p < 0.0001$), fasting insulin ($p < 0.05$), and insulin AUC ($p < 0.05$) compared to the control diet. From baseline to end of intervention, the fish diet (with weight maintenance) significantly increased plasma phospholipid n-3 fatty acids ($p < 0.0001$) and plasma phospholipid n-6 fatty acids ($p < 0.0001$) compared to the control group. From baseline to end of intervention, the change in fasting insulin levels and insulin AUC levels was significantly different in the fish group compared to the weight loss group and the fish + weight loss group ($p < 0.05$). There was no association found between diet group and change in fasting glucose or glucose AUC.	N
For first 2 months: Group 1 = 1530 mg EPA/1050 mg DHA Group 2 = olive oil placebo After 2 months until 6 months: Group 1 = 1020 mg EPA/700 mg DHA Group 2 = olive oil placebo Open phase from 6-12 months: 2 g/day of n-3 ethyl esters	No statistical differences could be detected between the two groups in terms of fasting glucose levels, HbAIc and insulinemia after 1 year of treatment.	N

continued

TABLE B-2g Continued

Author	Study Type	Subjects	Exposure
Grundt et al., 1995*	Randomized Controlled Trial	Men (n=51) Women (n=6) Aged 18-70 years Stavanger, Norway Outpatient center Has combined hyperlipidemia No dietary supplementation or medication containing omega-3 fatty acids during the run-in period, no antihyperlipemic medication No MI or other serious disease occurring within 3 months of enrollment, known diabetes mellitus, serious psychological disease, known drug or alcohol abuse, pregnancy or lactation Follow-up of 12 weeks	n-3 supplement
Kesavulu et al., 2002	Trial	Men and women (n=34) Nonobese, type II diabetic On oral antidiabetic drugs, but not on lipid lowering drugs or antioxidant therapy Normotensive; no other clinical complications other than diabetes, no diabetic complications Follow-up of 3 months	n-3 supplement

Amount	Results	Conclusion**
Treatment: 2 g concentrated ethylester compound 85% EPA/DHA Control: 2 g concentrated ethylester compound 85% corn oil	There were no statistical differences between the two groups or within the groups (between 2 weeks before treatment and after 12 weeks of treatment) with regards to serum glucose, plasma insulin, plasma proinsulin, insulin:glucose ratio, and proinsulin:glucose ratio.	N
Group 1 diabetics: 1 month of antidiabetic drugs alone 2 months of omega-3 supplement (1080 mg EPA and 720 mg DHA/day) along with the antidiabetic drugs Group 2 diabetics: 3 months of antidiabetic drugs alone Group 3: Non-diabetic controls	After combined therapy, fasting blood glucose and glycated hemoglobin were significantly higher in the Group 1 diabetics than in the controls ($p < 0.001$). After 3 months of antidiabetic treatment, there were no significant differences in fasting blood glucose and glycated hemoglobin between Group 2 diabetics and the controls.	B

continued

TABLE B-2g Continued

Author	Study Type	Subjects	Exposure
Madsen et al., 2001*	Cross-sectional	Men (n=171) Women (n=98) Aged 39-77 years Aalborg, Denmark Referred for coronary angiography because of clinical suspicion of CAD; clinically stable No acute myocardial infarction in past 6 months, nonischemic cardiomyopathy, pacemaker, or permanent tachyarrhythmias	PUFA in granulocyte membranes; seafood

*Included in Balk E, Chung M, Lichtenstein A, Chew P, Kupelnick B, Lawrence A, DeVine D, Lau J. 2004. *Effects of Omega-3 Fatty Acids on Cardiovascular Risk Factors and Intermediate Markers of Cardiovascular Disease. Summary, Evidence Report/Technology Assessment No. 83. (Prepared by the Tufts-New England Medical Center Evidence-based Practice Center, Boston, MA). AHRQ Publication No. 04-E034-3.* Rockville, MD: Agency for Healthcare Research and Quality.

**B = Evidence of a benefit; N = Evidence of no association or no clear association.

Amount	Results	Conclusion**
Fish Score: (sum for lunch and dinner, can range from 2-12) 1 = never eating fish 2 = eating fish 1 time/month 3 = eating fish 2-3 times/month 4 = eating fish 1 time/week 5 = eating fish 2-3 times/week 6 = eating fish at least 1 time/day	"Subjects with CRP levels in the lower quartiles had significantly higher contents of DHA in granulocytes than subjects with CRP levels in the upper quartile" (p=0.02). There were no significant associations found between CRP and LA, ALA, AA, EPA, or DPA content in granulocyte membranes or between CRP and fish score.	N

TABLE B-2h Studies on Adult Asthma and Allergies

Author	Study Type	Subjects	Exposure
Troisi et al., 1995	Cohort	Women (n=77,866) Aged 30-55 years US nurses Nurses' Health Study No diagnosed cancer, CVD, diabetes, emphysema, chronic bronchitis, or asthma before or at time of questionnaire Follow-up of 10 years	Dietary total fat and n-3 intake
Huang et al., 2001	Cross-sectional	Men (n=582) Women (n=584) Aged 13-17 years Taiwan Uninstitutionalized The National Nutritional Survey (1993-1996)	Seafood; diet

* N = Evidence of no association or no clear association; B = Evidence of a benefit.

Amount	Results	Conclusion*
Quintiles of total fat intake (median): 1 = 51.9 g 2 = 62.7 g 3 = 69.9 g 4 = 77.0 g 5 = 87.4 g	After adjusting for age, smoking, BMI, area of resi - dence, number of physician's visits, and quintiles of energy intake: There were no significant associations found between total fat intake, saturated fat intake, or omega-3 fat intake and the risk of asthma;	N
Quintiles of omega-3 (median): 1 = 0.05 g 2 = 0.09 g 3 = 0.13 g 4 = 0.21 g 5 = 0.36 g	Those in Quintile 3 of monounsaturated fat intake (median = 28.6 g) had a significantly lower RR of asthma than those in Quintile 1 (median = 20.1 g) (RR=0.74, 95% CI 0.59-0.93); and Those in Quintiles 2 and 4 of LA intake (median = 6 g and 11.1 g, respectively) had significantly lower RR of asthma than those in Quintile 1 (median = 4.49 g) (RR=0.71, 95% CI 0.57-0.89; RR=0.74, 95% CI 0.59-0.93; respectively).	
Quartiles of fish intake, absolute amounts unspecified	There were no significant differences found between the quartiles of all fish, shellfish, other seafood intake and prevalence of physician-diagnosed asthma (p=0.82, p=0.12, p=0.99, respectively). There was a significant difference among the quartiles of oily fish and the prevalence of physician-diagnosed asthma (quartile 1 = 1.5%, quartile 2 = 2.5%, quar - tile 3 = 4.6%, and quartile 4 = 4.9%; p=0.01). There were no significant differences found between the quartiles of all fish, oily fish, shellfish, other seafood intake and prevalence of physician-diagnosed allergic rhinitis (p=0.39, p=0.65, p=0.45, p=0.15, respectively).	B

TABLE B-2i Studies on Cancer

Author	Study Type	Subjects	Exposure
Stolzenberg-Solomon et al., 2002	Randomized Controlled Trial	Men (n=27,111) Aged 50-69 years Southwestern Finland Smoked ε5 cigarettes/day Alpha-tocopherol, Beta-Carotene Cancer Prevention (ATBC) Study No history of malignancy other than nonmelanoma cancer of the skin or carcinoma in situ, severe angina upon exertion, chronic renal insufficiency, liver cirrhosis, chronic alcoholism, receipt of anticoagulant therapy, other medical problems which might limit long-term participation, and current use of supplements containing vitamin E (>20 mg/day), vitamin A (>20,000 IU/day), or beta-carotene (>6 mg/day) Follow-up of up to 13 years (260,006 person-years)	Seafood; dietary fatty acids
MacLean et al., 2006	Review	Part of a larger systematic literature review Cohorts (n=20 cohorts; 38 articles) 11 different types of cancer	Seafood; dietary fatty acids

Amount	Results	Conclusion*
Randomized to 50 mg/day of alpha-tocopherol, 20 mg/day of beta-carotene, both, or placebo Quantiles of fish intake and n-3 fish oil intake, absolute amount unspecified	After adjusting for energy intake, age, and years of smoking, there were no significant associations found between quantities of fish intake or quantiles of n-3 fish oil intake and the risk of pancreatic cancer.	N
	"For each breast, lung, and prostate cancer, there were significant associations for both increased and decreased risk and far more estimates that did not demonstrate any association." "No trend was found across many different cohorts and many different categories of omega-3 fatty acid consumption to suggest that omega-3 fatty acids reduce overall cancer risk."	N

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Terry et al., 2003	Review	7 cohort studies on breast cancer 8 cohort studies on prostate cancer 1 cohort study on endometrial cancer 19 case-control studies on breast cancer 9 case-control studies on prostate cancer 7 case-control studies on endometrial cancer 5 case-control studies on ovarian cancer	Seafood, n-3 supplement, serum phospholipids, adipose tissue, and erythrocyte membrane fatty acids

Amount	Results	Conclusion*
	"The development and progression of breast and prostate cancers appear to be affected by processes in which EPA and DHA play important roles." However, "whether the consumption of fish containing marine fatty acids can alter the risk of these cancers or of other hormone-dependent cancers is unclear." "Although there is ample evidence from in vitro and animal studies that these essential fats can inhibit the progression of tumors in various organs, particularly the breast and prostate, the evidence from epidemiologic studies is less clear." "Although most of the studies did not show an association between fish consumption or marine fatty acid intake and the risk of hormone-related cancers, the results of the few studies from populations with a generally high intake of marine fatty acids are encouraging."	N

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Norat et al., 2005	Cohort	Men and women (n=478,040) Aged 35-70 years 23 centers in 10 European countries European Prospective Investigation into Cancer and Nutrition (EPIC) Recruited from general population Free of cancer at baseline, other than nonmelanoma skin cancer Average follow-up of 4.8 years (2,279,075 person-years)	Seafood

Amount	Results	Conclusion*
Categories of fish intake: 1 = <10 g/day 2 = 10-20 g/day 3 = 20-40 g/day 4 = 40-80 g/day 5 = ε80 g/day	After adjusting for age, sex, energy from nonfat sources, energy from fat sources, height, weight, occupational physical activity, smoking status, dietary fiber, alcohol intake, and stratified for center: Those in the 4th and 5th categories of fish intake had a significantly lower HR of colorectal cancer than those in the 1st category (HR=0.67, 95% CI 0.56-0.82; and HR=0.69, 95% CI 0.54-0.88, respectively). The HR for the 2nd and 3rd categories of fish intake were also lower compared to the 1st category, but they were not significant; Those in the 4th and 5th categories of fish intake had a significantly lower HR of rectal cancer than those in the 1st category (HR=0.64, 95% CI 0.47-0.88; and HR=0.49, 95% CI 0.32-0.76, respectively). The HR for the 2nd and 3rd categories of fish intake were also lower compared to the 1st category, but they were not significant; Those in the 4th category of fish intake had a significantly lower HR of colon cancer than those in the 1st category (HR=0.69, 95% CI 0.54-0.88). The HR for the 2nd, 3rd, and 5th categories of fish intake were also lower compared to the 1st category, but they were not significant; and Every 100 g increase in daily fish intake significantly lowered the HR for colorectal cancer (HR=0.70, 95% CI 0.57-0.87), colon cancer (HR=0.76, 95% CI 0.59-0.99), and rectal cancer (HR=0.61, 95% CI 0.43-0.87).	B

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Allen et al., 2004	Cohort	Men (n=18,115) Mean age at entry was 51 years Mean age at diagnosis was 75 years Hiroshima and Nagasaki, Japan Life Span Study/The Adult Health Study In Hiroshima or Nagasaki during the time of the bombs and who were residents of one of the cities in the 1950 census, or not present in either city at the time of the bombs No prostate cancer at baseline Average follow-up of 16.9 years (252,602 person-years)	Seafood
English et al., 2004	Cohort	Men and women (n=37,112) Aged 27-75 years Melbourne, Australia The Melbourne Collaborative Cohort Study Deliberately recruited Italian and Greek migrants Free of colorectal cancer, diabetes, a heart attack, or angina at baseline Average follow-up of 9 years	Seafood

Amount	Results	Conclusion*
Scores of intake for each food: 1 = Missing or <2 times/week 2 = 2-4 times/week 3 = Almost daily Total fish/broiled fish intake: Low = Score of 2 Intermediate = Score of 3-4 High = Score of ε5	After adjusting for age, calendar period, city of residence, radiation dose, and education level: Those who ate fish almost daily had a significantly higher RR of prostate cancer compared to those who ate fish <2 times/week (RR=1.54, 95% CI 1.03-2.31). Those who ate fish 2-4 times/week also had a higher RR of prostate cancer compared to those who ate fish <2 times/week, but this association was not significant (RR=1.18, 95% CI 0.83-1.67); There were no significant associations found between broiled fish intake and risk of prostate cancer; and Those in the highest category of total fish intake had a significantly higher RR of prostate cancer compared to those in the lowest category (RR=1.77, 95% CI 1.01-3.11). Those in the intermediate category also had a higher RR of prostate cancer compared to those in the lowest category, but this association was not significant (RR=1.19, 95% CI 0.82-1.73).	A
Categories of fish intake: 1 = < 1.0 time/week 2 = 1.0-1.4 times/week 3 = 1.5-2.4 times/week 4 = 2.5+ times/week	After adjusting for sex, country of birth, and intake of energy, fat, and cereal products: There were no significant associations found between fish intake (defined by four categories) and the risk of colorectal cancer, colon cancer, or rectal cancers; and There were no significant associations found between fish intake (defined as a continuous variable) and the risk of colorectal cancer (HR=0.99, 95% CI 0.91-1.08), colon cancer (HR=1.01, 95% CI 0.90-1.12), and rectal cancer (HR=0.97, 95% CI 0.84-1.12).	N

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Folsom and Demissie, 2004	Cohort	Women (n=41,836) Aged 55-69 years Iowa Iowa Women's Health Study Group 1 = no heart disease or cancer at baseline Group 2 = no cancer at baseline, but a history of myocardial infarction, angina, or other heart disease Follow-up of 442,965 person-years	Seafood; dietary fatty acids
Augustsson et al., 2003	Cohort	Men (n=47,882) Aged 40-75 years US health professionals Health Professionals Follow-up Study No diagnosis of cancer at baseline Follow-up of 12 years	Seafood

Amount	Results	Conclusion*
Categories of fish intake: 1 = <0.5 times/week 2 = 0.5-1.0 times/week 3 = 1.0-1.5 times/week 4 = >1.5-<2.5 times/week 5 = ε2.5 times/week Quintiles of omega-3 fatty acid intake: 1 = δ0.05 g/day 2 = 0.06-0.10 g/day 3 = 0.11-0.16 g/day 4 = 0.17-0.26 g/day 5 = ε0.27 g/day	After adjusting for age, energy intake, education level, physical activity, alcohol consumption, smoking status, pack-years of cigarette smoking, age at first live birth, estrogen use, vitamin use, BMI, waist/hip ratio, diabetes, hypertension, intake of whole grains, fruit and vegetables, red meat, cholesterol, and saturated fat: Among women with no cancer or heart disease at baseline, no significant associations were found between frequency of fish intake and risk of cancer mortality or breast cancer; and Among women with no cancer or heart disease at baseline, no significant associations were found between quintiles of omega-3 fatty acid intake and risk of total mortality or breast cancer incidence.	N
Categories of fish consumption: 1 = <2 times/month 2 = 2 times/month to 1 time/week 3 = 2-3 times/week 4 = >3 times/week	After adjusting for age, calories, fatty acids, lycopene, retinol, vitamin D, and physical activity: Those who ate fish >3 times/week had a significantly lower RR of metastatic prostate cancer than those who ate fish <2 times/month (RR=0.56, 95% CI 0.37-0.86). No other comparisons for metastatic prostate cancer were significant; There were no significant associations found between total fish consumption and all prostate cancer or advanced prostate cancer; and Each additional 0.5 g/day of marine fatty acids was associated with a RR of 0.76 (95% CI 0.58-0.98) for metastatic prostate cancer. "When fish intake was analyzed as a continuous variable, an increase in three servings of fish per week was associated with a RR of 0.75 (95% CI 0.60-0.94) for metastatic prostate cancer."	B

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Holmes et al., 2003	Cohort	Women (n=88,647) Aged 30-55 years US nurses Nurses' Health Study (NHS) No diagnosed cancer other than nonmelanoma skin cancer prior to 1980 Follow-up of 18 years	Seafood

Amount	Results	Conclusion*
Categories of fish intake: 1 = δ0.13 servings/day 2 = 0.14-0.20 servings/day 3 = 0.21-0.27servings/day 4 = 0.28-0.39 servings/day 5 = ε0.40 servings/day	After adjusting for age, 2-year time period, total energy intake, alcohol intake, parity and age at first birth, BMI at age 18, weight change since age 18, height in inches, family history of breast cancer, history of benign breast disease, age at menarche, menopausal status, age at menopause and hormone replacement therapy use, and duration of menopause: There was no significant association found between fish intake and the risk of breast cancer for the whole cohort or when premenopausal women and postmenopausal women were analyzed separately; and Similarly nonsignificant results were found when fish intake was defined as no intake, <1 serving/ day and ε1 serving/day.	N

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Stripp et al., 2003	Cohort	Women (n=23,693) Aged 50-64 years Copenhagen and Aarhus, Denmark Diet, Cancer and Health study No diagnosis of cancer at baseline Median follow-up of 4.8 years	Seafood

Amount	Results	Conclusion*
Lean fish = δ8 g/100 g Fatty fish = >8 g/100 g Percentiles of lean fish intake: 5th percentile = 7 g/day 25th percentile = 16 g/day 75th percentile = 32 g/day 95th percentile = 56 g/day Percentiles of fatty fish intake: 5th percentile = 2 g/day 25th percentile = 6 g/day 75th percentile = 19 g/day 95th percentile = 39 g/day Percentiles of fried fish intake: 5th percentile = 5 g/day 25th percentile = 13 g/day 75th percentile = 30 g/day 95th percentile = 55 g/day Percentiles of boiled fish intake: 5th percentile = 0 g/day 25th percentile = 4 g/day 75th percentile = 11 g/day 95th percentile = 23 g/day Percentiles of processed fish intake: 5th percentile = 2 g/day 25th percentile = 6 g/day 75th percentile = 19 g/day 95th percentile = 40 g/day	After adjusting for parity, benign breast tumor, years of school, use of hormone replacement therapy, duration of HRT use, BMI, and alcohol: Every 25 g/day increase in total fish consumption significantly increased the risk of breast cancer (IRR=1.13, 95% CI 1.03-1.23); and The risk of breast cancer is also increased for every 25 g/day increase in fatty fish (IRR=1.11, 95% CI 0.91-1.34), lean fish (IRR=1.13, 95% CI 0.99-1.29), fried fish (IRR=1.09, 95% CI 0.95-1.25), boiled fish (IRR=1.09, 95% CI 0.85-1.42), and processed fish (IRR=1.12, 95% CI 0.93-1.34), but the IRR were not.	A

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Takezaki et al., 2003	Cohort	Men (n=2798) Women (n=3087) Aged 40-79 years Aichi Prefecture, Japan Rural area Follow-up of 14 years	Seafood

Amount	Results	Conclusion*
Categories of fish and shellfish intake: Low = <1 time/week Middle = 1-2 times/week High = ε3 times/week	After adjusting for age, sex, smoking, and occupation, those in the high-fish and -shellfish intake category had a significantly lower RR for incident lung cancer than those in the low category (RR=0.32, 95% CI 0.13-0.76) (p for trend = 0.003). The middle intake group also had a smaller RR but it was not significant (RR=0.99, 95% CI 0.48-2.03). After adjusting for age, sex, smoking, and occupation: Those in the middle and high categories of total fish intake (regardless of preparation method) had a significantly lower RR for incident lung cancer than those in the low category (RR=0.43, 95% CI 0.20-0.95; and RR=0.23, 95% CI 0.10-0.54; respectively); Those in the high categories of broiled and boiled fish intake had significantly lower RR for incident lung cancer than those in the low categories (RR=0.40, 95% CI 0.17-0.93; and RR=0.27, 95% CI 0.09-0.81; respectively). Those in the middle categories of broiled and boiled fish intake also had lower RR for incident lung cancer than those in the low category but they were not significant; and There were no significant associations found between raw or deep-fried fish intake and the risk of incident lung cancer. Similar results were found when the model further adjusted for drinking, exercise habit, consumption of meat, green-yellow vegetables, and salty/dried fish.	B

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Ngoan et al., 2002	Cohort	Men (n=5917) Women (n=7333) Aged >15 years Fukuoka Prefecture, Japan Follow-up of 139,390 person-years	Seafood
Ozasa et al., 2001	Cohort	Men (n=42,940) Women (n=55,308) Aged 40-79 years 19 prefectures throughout Japan Japanese Collaborative Cohort (JACC) Study No history of lung cancer Average follow-up of 92 months	Seafood
Terry et al., 2001	Cohort	Men (n=6272) Mean age of 55.6 years (baseline) Twin pairs from the Sweden Twin registry Sweden Follow-up of 30 years	Seafood

Amount	Results	Conclusion*
Categories of cuttle fish intake: Low = seldom or never Medium = 2-4 times/month High = 2-4 times or more/week Categories of fish intake: Low = 2-4 times or less/month Medium = 2-4 times/week High = 1 time or more/day	After adjusting for age, there was no significant association found between intake of fresh fish, processed fish, or cuttle fish and the risk of stomach cancer among men and women. After adjusting for age, sex, smoking, processed meat, liver, cooking or salad oil, suimono, and pickled food, there was no significant association found between intake of fresh fish, processed fish, or cuttle fish either including the first 3 years of follow-up or excluding the first 3 years of follow-up.	N
Categories of fish intake: 1 = δ1-2 times/week 2 = 3-4 times/week 3 = Almost every day	After adjusting for age, parents' history of lung cancer, smoking status, smoking index and time since quitting smoking, there was no significant association found between fish intake and risk of lung cancer death in men or women.	N
Categories of fish intake: 1 = Never/seldom part of diet 2 = Small part of diet 3 = Moderate part of diet 4 = Large part of diet	After adjusting for age, BMI, physical activity, smoking, and consumption of alcohol, red meat, processed meat, fruit and vegetables, and milk: Those who never or seldomly ate fish had a significantly higher RR of all prostate cancers than those who made fish a moderate part of their diet (RR=2.3, 95% CI 1.2-4.5, $p < 0.05$); Those who never or seldomly ate fish had a significantly higher RR of prostate cancer deaths than those who made fish a moderate part of their diet (RR=3.3, 95% CI 1.8-6.0, $p < 0.01$); and No other comparisons between fish consumption and all prostate cancers or prostate cancer deaths were significant.	B

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Key et al., 1999	Cohort	Women (n=34,759) Hiroshima and Nagasaki, Japan Life Span Study In Hiroshima or Nagasaki during the time of the bombs and city residents during the 1950 census, or not in either city at the time of the bombs Follow-up of 488,989 person-years	Seafood
Kato et al., 1997	Cohort	Women (n=14,727) Aged 34-65 years New York and Florida New York University Women's Health Study No use of hormonal medication or pregnancy in preceding 6 months Follow-up of 105,044 person-years	Seafood

Amount	Results	Conclusion*
Categories of fish intake: 1 = δ 1 time/week 2 = 2-4 times/week 3 = ε5 times/week 4 = Unknown	After adjusting for attained age, calendar period, city, age at time of bombing, and radiation dose: There were no significant associations found between categories of fish (not dried) intake and risk of breast cancer; and Those in the "unknown" category of dried fish intake had a significantly lower RR of breast cancer than those in the 1st category (RR=0.77, 95% CI 0.60-0.98). No other comparisons for dried fish intake were significant.	N
Quartile of fish intake, absolute amounts not specified	After adjusting for calories intake, age, place at enrollment, and highest level of education: Those in the 4th quartile of fish intake had a significantly lower RR of colorectal cancer compared to those in the 1st quartile (RR=0.49, 95% CI 0.27-0.89). The RR for those in the 2nd and 3rd quartiles were not significant (p for trend = 0.007); Those in the 4th quartile of fish protein intake had a significantly lower RR of colorectal cancer compared to those in the 1st quartile (RR=0.42, 95% CI 0.23-0.77). The RR for those in the 2nd and 3rd quartiles were also lower but not significant (p for trend = 0.016); Those in the 4th quartile of fish calcium intake had a significantly lower RR of colorectal cancer compared to those in the 1st quartile (RR=0.41, 95% CI 0.22-0.74). The RR for those in the 2nd and 3rd quartiles were also lower but not significant (p for trend = 0.001); and No significant association was found between fish fat intake and risk of colorectal cancer (p for trend = 0.056).	B

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Veierod et al., 1997	Cohort	Men (n=25,956) Women (n=25,496) Aged 16-56 years Norway Attended Norwegian health screening between 1977 and 1983 Average follow-up of 11.2 years (578,047 person-years)	Seafood; n-3 supplements
Chiu et al., 1996	Cohort	Women (n=35,156) Aged 55-69 years Iowa Iowa Women's Health Study No self-reported history of cancer at baseline or prior use of chemotherapy Follow-up of 7 years (233,261 person-years)	Seafood

Amount	Results	Conclusion*
Cod-liver oil intake: yes or no	After adjusting for smoking status, gender, age at inclusion, and attained age:	B
Sardines, pickled herring (sandwich spread): yes or no	Those taking cod liver oil had a lower incidence rate ratio of lung cancer compared to those not taking cod liver oil (IRR=0.5, 95% CI 0.3-1.0), but it was not significant;	
Categories of fish liver intake: 1 = <1 time/week in season 2 = 1-2 times/week in season 3 = ε3 times/week in season	Those who consumed sardines and pickled herring had a significantly higher incidence rate ratio compared to those not consuming sardines and pickled herring (IRR=1.5, 95% CI 1.1-2.2);	
Categories of main meals with fish: 1 = <1 time/week 2 = 1-2 times/week 3 = 3-4 times/week 4 = ε5 times/week	Those who consumed fish liver ε3 times/week in season had a significantly higher incidence rate ratio of lung cancer compared to those who consumed fish liver <1 time/week in season (IRR=2.6, 95% CI 1.2-6.0). Those who consumed fish liver 1-2 times/week in season also had a higher incidence rate ratio compared to those who consumed fish liver <1 time/week in season (IRR=1.1, 95% CI 0.7-1.7), but it was not significant; and Those who consumed main meals with fish ε5 times/week had a significantly higher incidence rate ratio of lung cancer compared to those who ate main meals with fish <1 time/week (IRR=3.0, 95% CI 1.2-7.3). Those who consumed main meals with fish 1-2 times/week and 3-4 times/ week also had higher incidence rate ratios of lung cancer compared to those who consumed main meals with fish <1 time/week (IRR=1.1, 95% CI 0.6-2.2; and IRR=1.0, 95% CI 0.5-2.1), but they were not significant.	
Categories of fish intake: 1 = <4 servings/month 2 = 4-6 servings/month 3 = >6 servings/month	After adjusting for age and total energy intake, there were no significant associations found between intake of all fish or polyunsaturated fat and risk of non-Hodgkins lymphoma.	N

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Chyou et al., 1995	Cohort	Men (n=7995) Born in 1900-1919 Examined from 1965-1968 Oahu, Hawaii American men of Japanese ancestry Participated in the Honolulu Heart Program Follow-up of 24 years	Seafood
Giovannucci et al., 1994	Cohort	Men (n=47,949) Aged 40-75 years US health professionals Health Professionals Follow-up Study No diagnosed cancer at baseline	Seafood
Le Marchand et al., 1994	Cohort	Men (n=20,316) Aged <45 years Permanent resident of Hawaii Nonmilitary Japanese, Caucasian, Filipino, Hawaiian/part Hawaiian, and Chinese No invasive cancer within 5 years before entry, no diagnosis of prostate cancer earlier than 5 years before interview Median follow-up of 6 years (between entry and diagnosis for cases)	Seafood
Chyou et al., 1993	Cohort	Men (n=7995) Born in 1900-1919 Examined from 1965-1968 Oahu, Hawaii American men of Japanese ancestry Participated in the Honolulu Heart Program Follow-up of 22 years	Seafood

Amount	Results	Conclusion*
Categories of fish intake: 1 = δ1 serving/week 2 = 2-4 servings/week 3 = ε5 servings/week	After adjusting for age, alcohol, number of cigarettes/day and number of years smoked: There was no significant association found between fish intake and the risk of upper aerodigestive tract cancer (RR=1.02, 95% CI 0.65-1.61 for 2-4 times/week compared to δ1 time/week; and RR=1.37, 95% CI 0.70-2.69 for ε5 times/week compared to δ1 time/week).	N
Categories of fish intake (median): 1 = 8.4 g/day 2 = 20.9 g/day 3 = 31.0 g/day 4 = 47.8 g/day 5 = 83.4 g/day	After adjusting for age, there was no significant association found between fish intake and the risk of colon cancer.	N
Quantile of fish intake, absolute amounts not specified	After adjusting for age, ethnicity, and income, no significant association was found between risk of prostate cancer and quantile of fish intake at baseline.	N
Categories of fish intake: 1 = δ1 serving/week 2 = 2-4 servings/week 3 = ε5 servings/week	After adjusting for age and smoking, there was no significant association found between fish intake and bladder cancer (RR=0.90, 95% CI 0.59-1.39 for 2-4 times/week compared to δ1 time/week; and RR=0.67, 95% CI 0.26-1.67 for ε5 times/week compared to δ1 time/week).	N

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Vatten et al., 1990	Cohort	Women (n=14,500) Aged 35-51 years Norway Participated in the National Health Screening Service Follow-up of 11-14 years (mean = 12 years)	Seafood
Willett et al., 1990	Cohort	Women (n=88,751) Aged 30-55 years US nurses Nurses' Health Study (NHS) No history of cancer, inflammatory bowel disease, or familial polyposis at baseline Follow-up of 6 years (512,488 person-years)	Seafood

Amount	Results	Conclusion*
Categories of overall fish intake: 1 = δ2 times/week 2 = >2 times/week Categories of poached fish intake: 1 = <2 times/month 2 = 2-4 times/month 3 = ε5 times/month	After adjusting for age: Those who ate fish >2 times/week had a higher IRR of breast cancer when compared to those who ate fish δ2 times/week, but it was not significant (IRR=1.2, 95% CI 0.8-1.7); and Those who ate poached fish 2-4 times/month and ε5 times/month had lower IRR of breast cancer when compared to those who ate poached fish <2 times/week, but they were not significant (IRR=0.8, 95% CI 0.5-1.1; and IRR=0.7, 95% CI 0.4-1.0; respectively).	N
Categories of fish intake: 1 = <1 time/month 2 = 1-3 times/month 3 = 1 time/week 4 = 2-4 times/week 5 = ε5 times/week Quintiles of chicken and fish intake: 1 = <22 g/day 2 = 22-28 g/day 3 = 29-40 g/day 4 = 41-64 g/day 5 = ε65 g/day	After adjusting for age, there was no significant association found between fish intake and incidence of colon cancer. After adjusting for age and total energy intake: Those in the 4th and 5th quintiles of chicken and fish intake had significantly lower RR of colon cancer compared to those in the 1st quintile (RR=0.47, 95% CI 0.27-0.81; and RR=0.56, 95% CI 0.34-0.92; respectively); and Those in the 2nd and 3rd quintiles of chicken and fish intake also had lower RR of colon cancer compared to those in the 1st quintile (RR=0.75, 95% CI 0.46-1.22; and RR=0.99, 95% CI 0.63-1.54; respectively), but they were not significant.	N

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Mills et al., 1989	Cohort	Men (n=about 15,000) Aged ε25 years California Seventh-day Adventists Follow-up of 6 years (78,000 person-years)	Seafood
Kvale et al., 1983	Cohort	Men (n=13,785) Women (n=2928) Men in a probability sample of the general population of Norway A roster of male siblings, living in Norway, of migrants to the US Male and female family members of patients interviewed in a Norwegian case-control study of gastrointestinal cancer Follow-up of 11.5 years	Seafood
Pan et al., 2004	Case-control	Cases = with incident ovarian cancer (n=442) Controls = without cancer from eight provinces, except Manitoba (n=2135) Women Mean age of 55 years Canada National Enhanced Cancer Surveillance Study (NECSS)	Seafood; dietary fatty acids

Amount	Results	Conclusion*
Categories of fish intake: 1 = Never 2 = <1 time/week 3 = ε1 time/week	After adjusting for age: Those who ate fish <1 time/week had a significantly higher RR of prostate cancer compared to those who never ate fish (RR=1.68, 95% CI 1.16-2.43); and Those who ate fish ε1 time/week also had a higher relative risk of prostate cancer compared to those who never ate fish, but it was not significant (RR=1.47, 95% CI 0.84-2.60). After adjusting for age; education; current use of meat, poultry or fish, beans, legumes or peas, citrus fruit, dry fruit; and index of fruit, nuts, and tomatoes: No significant association was found between current use of fish and prostate cancer risk (RR=1.37, 95% CI 0.95-1.96 for <1 time/week compared to never and RR=1.57, 95% CI 0.88-2.78 for ε1 time/week compared to never).	A
Index of frequency of fish intake (scores): 1 = <10 2 = 10-14 3 = 15-19 4 = ε20	After adjusting for age, cigarette smoking, region, and urban/rural place of residence, no significant association was found between the fish intake (the highest score of fish intake compared to the lowest score of fish intake) and the risk of lung cancer, with either histologically verified primary tumor (″=−0.07±0.13, p=0.63) or squamous and small-cell carcinomas (″=−0.01±0.17, p=0.99).	N
Serving size=4 oz/week Quartiles of fish and fatty acid intakes, absolute amount unspecified	After adjusting for 10-year age group, province of residence, education, alcohol consumption, cigarette pack-years, BMI, total caloric intake, recreational physical activity, number of live births, menstruation years, and menopause status: There were no significant associations found between fish intake or fatty acid intake (saturated, monounsaturated, or polyunsaturated) and risk of ovarian cancer.	N

continued

TABLE B-2i Continued

Author	Study Type	Subjects	Exposure
Goldbohm et al., 1994	Case-cohort	Men (n=1688) Women (n=1812) Aged 55-69 years Netherlands Based on incident cases of colon cancer Subcohort of Netherlands Cohort Study Follow-up of over 3.3 years	Seafood; dietary fatty acids
Larsson et al., 2004	Review	Case-control, cohort, and animal studies	Seafood; n-3 supplements

*N = Evidence of no association or no clear association; B = Evidence of a benefit; A = Evidence of an adverse effect.

Amount	Results	Conclusion*
Categories of fish intake: 1 = 0 g/day 2 = 0-10 g/day 3 = 10-20 g/day 4 = >20 g/day Quintiles of fatty acids	After adjusting for age and energy: Men in the 3rd category of fish intake had a significantly lower RR of colon cancer compared to men in the 1st category of fish intake (RR=0.41, 95% CI 0.21-0.83). No other significant relative risks of colon cancer were found based on fish intake for men, women, or both sexes; and No significant associations were found between risk of colon cancer and intake of energy, fat, saturated fat, monounsaturated fat, polyunsaturated fat, or protein for among men, women, or both sexes.	B
	"Increasing evidence from animal and in vitro studies indicates that n-3 fatty acids, especially the long-chain polyunsaturated fatty acids EPA and DHA, present in fatty fish and fish oils, inhibit carcinogenesis." "The epidemiologic data on the association between fish consumption, as a surrogate marker for n-3 fatty acid intake, and cancer risk are, however, somewhat less consistent." n-3 fatty acids may modify the carcinogenic process by suppressing AA-derived eicosanoid biosynthesis; influencing transcription factor activity, gene expression, and signal transduction pathways; modulating estrogen metabolism; increasing or decreasing the production of free radicals and reactive oxygen species; and influencing insulin sensitivity and membrane fluidity.	N

TABLE B-2j Studies on Aging and Other Neurological Outcomes

Author	Study Type	Subjects	Exposure
Chen et al., 2003	Cohort	Men with incident Parkinson's disease (n=191) Women with incident Parkinson's disease (n=168) Data from Health Professionals Follow-up Study and Nurses' Health Study No Parkinson's disease, stroke, or cancer at baseline Follow-up of 2 years	Dietary fatty acids

Amount	Results	Conclusion*
Quintiles of polyunsaturated fatty acids, fish n-3 fatty acids, EPA, and DHA; absolute amounts not specified	After adjusting for baseline age, length of follow-up, smoking, energy intake, alcohol consumption, and caffeine intake: There were no significant associations found between quintiles of polyunsaturated fatty acids, fish n-3 fatty acids, EPA, or DHA and risk of Parkinson's disease.	N

continued

TABLE B-2j Continued

Author	Study Type	Subjects	Exposure
Morris et al., 2003	Cohort (nested in a randomized controlled trial)	Men and women (n=815) Aged ε65 years Chicago, IL (south-side) 62% Black, 38% White, 61% female, mean education level 11.8 years Chicago Health and Aging Project Free of Alzheimer's disease at baseline follow-up of 3 years	Seafood and dietary n-3 fatty acids

Amount	Results	Conclusion*
Quintiles of n-3 fatty acids (g/day): 0.37-1.05, 1.06-1.22, 1.23-1.39, 1.40-1.60, 1.61-4.10 Categories of fish intake: Never, 1-3 times/month, 1 time/week, ε2 times/week	After adjusting for age, period of observation, and fish consumption (1-3 times/months, 1 time/week, and ε2 times/week): There were no significant associations found between fish consumption and risk of incident Alzheimer's disease; Those in the 5th quintile of total n-3 fatty acid intake had a significantly lower RR of incident Alzheimer's disease than those in the 1st quintile (RR=0.3, 95% CI 0.1-0.7); and Those in the 4th quintile of DHA intake had a significantly lower RR of incident Alzheimer's disease than those in the 1st quintile (RR=0.3, 95% CI 0.1-0.9). After adjusting for age, period of observation, fish consumption (1-3 times/month, 1 time/week, and ε2 times/week), sex, race, education, total energy intake, APOE-∝4, and race · APOE-∝4 interaction: The higher categories of fish intake had lower RR of incident Alzheimer's disease compared to those who never ate fish (RR=0.6, 95% CI 0.3-1.3 for 1-3 times/month; RR=0.4, 95% CI 0.2-0.9 for 1 time/week; and RR=0.4, 95% CI 0.2-0.9 for ε2 times/week); Those in the 5th quintile of total n-3 fatty acid intake had a significantly lower RR of incident Alzheimer's disease than those in the 1st quintile (RR=0.4, 95% CI 0.1-0.9); and Those in the 4th and 5th quintiles of DHA intake had a significantly lower RR of incident Alzheimer's disease than those in the 1st quintile (RR=0.2, 95% CI 0.1-0.8; and RR=0.3, 95% CI 0.1-0.9; respectively). There were no other significant associations found between intake of n-3 fatty acids, DHA, EPA, and LA and the risk of incident Alzheimer's disease.	B

continued

TABLE B-2j Continued

Author	Study Type	Subjects	Exposure
Barberger-Gateau et al., 2002	Cohort	Men and women (n=1674) Aged ε68 years Southwestern France Personnes Agees QUID (PAQUID study)—third wave of study Free of dementia at baseline and living at home Follow-up of 7 years	Seafood

Amount	Results	Conclusion*
Categories of fish or seafood consumption: 1 = Once a day 2 = At least once a week (but not everyday) 3 = From time to time (but not weekly) 4 = Never	After adjusting for age and sex, those who ate fish or seafood at least once a week had a significantly lower risk of being diagnosed with dementia in the 7 years of follow-up (HR=0.66, 95% CI 0.47-0.93). After adjusting for age and sex, those who ate fish or seafood at least once a week had a lower risk of developing Alzheimer's disease in the 7 years of follow-up (HR=0.69, 95% CI 0.47-1.01), with borderline significance. After adjusting for age, sex, and education, those who ate fish or seafood at least once a week had a lower risk of being diagnosed with dementia in the 7 years of follow-up (HR=0.73, 95% CI 0.52-10.3), but it was not significant. There was a "significant trend between increasing consumption of fish or seafood and decreasing incidence of dementia (p for trend = 0.0091)."	B

continued

TABLE B-2j Continued

Author	Study Type	Subjects	Exposure
Kalmijn et al., 1997a	Cohort	Men and women (n=5386) Aged >55 years Rotterdam, Netherlands Rotterdam Study About 43% former smokers, about 23% current smokers About 2% history of stroke, about 7% history of myocardial infarction Average follow-up of 2.1 years	Dietary fatty acids
Zhang et al., 2000	Cohort	Women (n=92,422 in NHS, n=95,389 in NHS II) Aged 30-55 years in NHS Aged 25-42 years in NHS II US nurses living in 11 states Nurses' Health Study (NHS) and Nurses' Health Study II (NHS II)—pooled Follow-up of 14 years in NHS and 4 years in NHS II	Seafood and dietary fatty acids

Amount	Results	Conclusion*
Tertiles of total fat intake: δ75.5 g/day, 75.5-85.5 g/day, >85.5 g/day Tertiles of saturated fat intake: δ29.0 g/day, 29.0-34.0 g/day, >34.0 g/day Tertiles of cholesterol intake: δ208.5 mg/day, 208.5-254.5 mg/day, >254.5 mg/day Tertiles of LA intake: δ9.5 g/day, 9.5-15.0 g/day, >15.0 g/day Tertiles of fish intake: δ3.0 g/day, 3.0-18.5 g/day, >18.5 g/day	After adjusting for age, sex, education, and total energy: Those in the 3rd tertile of total fat intake had a significantly higher RR of total dementia than those in the 1st tertile (RR=2.4, 95% CI 1.1-5.2). Those in the 2nd tertile also had a higher RR of total dementia compared to those in the 1st tertile, but it was not significant; Those in the 3rd tertile of fish intake had a significantly lower RR of total dementia (RR=0.4, 95% CI 0.2-0.9) and Alzheimer's disease without cerebrovascular disease (RR=0.3, 95% CI 0.1-0.9) than those in the 1st tertile. Those in the 2nd tertile also had a lower RR of total dementia and Alzheimer's disease without cerebrovascular disease compared to those in the 1st tertile, but they were not significant; and No other significant RR were found for total dementia, Alzheimer's disease without cerebrovascular disease, or dementia with a vascular component based on daily intake of total fat, saturated fat, cholesterol, LA and fish.	B
Categories of fish intake: 1 = <1 time/week 2 = 1-2.9 times/week 3 = 3-4.9 times/week Quintiles of total energy, total fat, animal fat, vegetable fat, saturated fat, monounsaturated fat, n-6 polyunsaturated fat, trans-unsaturated fat, cholesterol; absolute amounts not specified	After adjusting for age, total energy, tier at birth, and pack-years of smoking: There were no significant RR of multiple sclerosis based on one unit daily increments of oleic acid (RR=0.7, 95% CI 0.4-1.4), LA (RR=0.3, 95% CI 0.1-1.1), AA (RR=0.9, 95% CI 0.7-1.2), fish omega-3 fatty acids (RR=1.1, 95% CI 0.9-1.3), EPA (RR=1.3, 95% CI 0.9-1.9), or DHA (RR=1.1, 95% CI 0.9-1.5) ; There were no significant RR of multiple sclerosis based on categories of fish and other seafood (RR=1.0, 95% CI 0.8-1.4 for category 2 compared to category 1; RR=0.9, 95% CI 0.6-1.3 for category 3 compared to category 1).	N

continued

TABLE B-2j Continued

Author	Study Type	Subjects	Exposure
Kalmijn et al., 1997b	Cohort	Men (n=939) Aged 69-89 years Zutphen, Netherlands The Zutphen Elderly Study (continuation of the Zutphen Study) Follow-up of 3 years	Dietary fatty acids
Ghadirian et al., 1998	Case-control	Cases = incident MS patients (n=197) Controls = from general population (n=202) Men and women Mean age of 42 years for male cases Mean age of 37.5 years for female cases Montreal, Canada	Seafood

Amount	Results	Conclusion*
Total energy, n-6 PUFA, n-3 PUFA, fish as continuous variables	No significant differences in the change in daily intake of total energy, n-6 PUFA, n-3 PUFA, or fish from 1985-1990 were found between those with normal and impaired cognitive function.	N
Tertiles of n-3 fatty acids intake: Low = 0.0-37.5 mg/day Medium = 37.5-155.5 mg/day High = 155.5-2110.5 mg/day	Those with normal cognitive function had significantly higher mean daily intakes of energy (p=0.03), DHA (p=0.05), and fish (p=0.02); and significantly lower mean daily intakes of total fat (p=0.02), total PUFA (p=0.002), and LA (p=0.006) than those with impaired cognitive function. The adjusted OR for prevalent cognitive impairment are OR=1.09 (95% CI 0.65-1.80) for medium n-3 fatty acid intake and OR=0.96 (95% CI 0.57-1.62) for high n-3 fatty acid intake compared to the low n-3 fatty acid intake (p for trend = 0.9). They are not significant. The adjusted OR for cognitive decline are OR=0.85 (95% CI 0.40-1.82) for medium n-3 fatty acid intake and OR=0.78 (95% CI 0.35-1.73) for high n-3 fatty acid intake compared to the low n-3 fatty acid intake (p for trend = 0.5). They are not significant.	
100 g increments of intake/day	After adjusting for total energy and BMI, every 100 g increase in daily fish intake decreases the risk of multiple sclerosis (OR=0.91, 95% CI 0.78-1.05). For males this statistic is 1.08 (95% CI 0.84-1.40), and for females this statistic is 0.83 (95% CI 0.69-1.00).	B (females only)

continued

TABLE B-2j Continued

Author	Study Type	Subjects	Exposure
Petridou et al., 1998	Case-control	Cases = with cerebral palsy (n=91) Controls = no cerebral palsy, from same study base as the cases (series1 = closest neighbor of similar sex and age as the case; series2 = first neurological patient seen by attending physicians after a visit by the case, with a healthy sibling of similar sex and age as the case) (n=246) Children Aged about 4-9 years Athens, Greece	Seafood

* N = Evidence of no association or no clear association; B = Evidence of a benefit.

Amount	Results	Conclusion*
Categories of fish/fish product intake: 1 = <1 time/week 2 = 1 time/week 3 = >1 time/week	After adjusting for age of child, sex, maternal age at delivery, maternal age at menarche, maternal chronic disease, previous spontaneous abortions, persistent vomiting during index pregnancy, multiple pregnancy, number of obstetric visits, timing of membrane rupture in relation to index delivery, use of general anaesthesia in the index delivery, mode of delivery, abnormal placenta, head circumference, evident congenital malformation, place of index delivery, use of supplementary Fe during index pregnancy, intentional physical exercise during index pregnancy, painless delivery classes, energy intake, cereals and starchy roots, sugars and syrups, pulses and nuts/seeds, vegetables, fruits, meat and meat products, milk and milk products, and oils and fats: Each one weekly serving increase in fish and fish products during pregnancy lowered the odds of having a child with cerebral palsy (OR=0.63, 95% CI 0.37-1.08, p=0.09), but this statistic was not significant.	N

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Recommendations for Seafood and EPA/DHAConsumption

TABLE B-3 Recommendations for Seafood and EPA/DHA Consumption

Organization	Audience	Purpose of Recommendtion
American Heart Association	Healthy adults (without documented coronary heart disease)	Reduce cardiovascular disease by dietary and lifestyle facts among the general population
American Heart Association	People with documented heart disease	Secondary prevention
American Heart Association	People with elevated triglycerides	Lower triglycerides
Dietary Guidelines Advisory Committee	Unspecified	Provide sound and current dietary guidelines to consumers
MyPyramid	Americans	Help Americans make healthy food choices, given their sex, age, and activity level
National Cholesterol Education Program, National Heart, Lung, and Blood Institute	People with high LDL-cholesterol/those adopting therapeutic lifestyle changes (TLC)	Healthy lifestyle recommendation for a healthy heart
American Diabetes Association	Unspecified	Lower risk of diabetes, and protect your heart and blood vessels
World Health Organization	Unspecified	To protect against coronary heart disease and ischaemic stroke
European Society of Cardiology	General population	To offer advice on food choices to compose a diet associated with the lowest risk of cardiovascular disease
United Kingdom Scientific Advisory Committee on Nutrition	General population and pregnant women	To reduce risk of cardiovascular disease
European Food Safety Authority	Unspecified	Reach daily intake for LC n-3 PUFA recommended for potential benefits to health
National Heart Foundation of Australia	People with coronary heart disease	Preventing cardiovascular events

Recommendations		
Type of Fish/Seafood	Serving size	# of Servings
All fish, particularly fatty fish (salmon, albacore tuna, mackerel, lake trout, herring, and sardines)	3 ounces cooked (or 4 ounces raw)	Two per week
EPA+DHA per day, preferably from fatty fish; supplements can be considered with physician consultation	1 gram EPA+DHA	One per day
EPA+DHA per day as a capsule with physician consultation	2-4 grams EPA+DHA	One per day
Fish, especially salmon, trout, white (albacore or bluefin) tuna, mackerel, or other fish that are high in EPA and DHA	4 ounces	Two per week
Fish rich in omega-3 fatty acids, such as salmon, trout, and herring	Not specified	More often
Fish, type unspecified	δ5 ounces	One per day
Fish	Not specified	2–3 per week
Fish, type unspecified	Equivalent to 200–500 mg of EPA+DHA	1–2 per week
Fish, particularly oily fish	Not specified	Consumption encouraged
Fish	Not specified	Two per week, one of which should be oil fish (H450 mg/day of LCPUFA)
Fish, especially fatty fish	130 grams	1–2 per week
Fish, preferably oily fish	Unspecified	At least 2 per week

FDA and EPA Safety Levels in Regulations and Guidance

TABLE B-4 FDA and US EPA Safety Levels in Regulations and Guidance

Product	Level	Reference
Ready-to-eat fishery products (minimal cooking by consumer)	Enterotoxigenic *Escherichia coli* (ETEC)—1 · 10^3 ETEC/gram, LT or ST positive.	Compliance Program 7303.842
Ready-to-eat fishery products (minimal cooking by consumer)	*Listeria monocytogenes*—presence of organism.	Compliance Program 7303.842
All fish	*Salmonella* species—presence of organism.	Sec 555.300 Compliance Policy Guide
All fish	1. *Staphylococcus aureus*—positive for staphylococcal enterotoxin, or 2. *Staphylococcus aureus* level is equal to or greater than 10^4/gram (MPN).	Compliance Program 7303.842
Ready-to-eat fishery products (minimal cooking by consumer)	*Vibrio cholerae*—presence of toxigenic 01 or non-01.	Compliance Program 7303.842
Ready-to-eat fishery products (minimal cooking by consumer)	*Vibrio parahaemolyticus*—levels equal to or greater than 1 · 10^4/gram (Kanagawa positive or negative).	Compliance Program 7303.842
Ready-to-eat fishery products (minimal cooking by consumer)	*Vibrio vulnificus*—presence of pathogenic organism.	Compliance Program 7303.842
All fish	*Clostridium botulinum*— 1. Presence of viable spores or vegetative cells in products that will support their growth, or 2. Presence of toxin.	Compliance Program 7303.842
Clams and oysters, fresh or frozen—imports	Microbiological— 1. *E. coli*—MPN of 230/100 grams (average of subs or 3 or more of 5 subs); 2. APC—500,000/gram (average of subs or 3 or more of 5 subs).	Sec 560.600 Compliance Policy Guide

continued

TABLE B-4 Continued

Product	Level	Reference
Clams, oysters, and mussels, fresh or frozen—domestic	Microbiological— 1. *E. coli* or fecal coliform—1 or more of 5 subs exceeding MPN of 330/100 grams or 2 or more exceeding 230/100 grams; 2. APC—1 or more of 5 subs exceeding 1,500,000/gram or 2 or more exceeding 500,000/gram.	Compliance Program 7303.842
Salt-cured, air-dried uneviscerated fish	Not permitted in commerce (Note: small fish exemption).	Sec 540.650 Compliance Policy Guide
Tuna, mahi mahi, and related fish	Histamine—500 ppm based on toxicity. 50 ppm defect action level, because histamine is generally not uniformly distributed in a decomposed fish. Therefore, 50 ppm is found in one section, there is the possibility that other units may exceed 500 ppm.	Sec 540.525 Compliance Policy Guide
All fish	Polychlorinated Biphenyls (PCBs)—2 ppm (edible portion).[a]	21 CFR 109.30
Fin fish and shellfish	Aldrin and dieldrin—0.3 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
Frog legs	Benzene hexachloride—0.3 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Chlordane—0.3 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Chlordecone—0.4 ppm crabmeat and 0.3 ppm in other fish (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	DDT, TDE, and DDE—5 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Heptachlor and heptachlor epoxide—0.3 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Mirex—0.1 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Diquat—0.1 ppm.[a]	40 CFR 180.226

continued

TABLE B-4 Continued

Product	Level	Reference
Fin fish and crayfish	Fluridone—0.5 ppm.[a]	40 CFR 180.420
Fin fish	Glyphosate—0.25 ppm.[a]	40 CFR 180.364
Shellfish	Glyphosate—3 ppm.[a]	40 CFR 180.364
Fin fish	Simazine—12 ppm.[a]	40 CFR 180.213a
All fish	2,4-D—1 ppm.[a]	40 CFR 180.142
Salmonids, catfish, and lobster	Oxytetracycline—2 ppm.	21 CFR 556.500
All fish	Sulfamerazine—no residue permitted.	21 CFR 556.660
Salmonids and catfish	Sulfadimethoxine/ormetoprim combination—0.1 ppm.	21 CFR 556.640
All fish	Unsanctioned drugs[b]—no residue permitted.	Sec 615.200 Compliance Policy Guide
Crustacea	Toxic elements: 76 ppm arsenic; 3 ppm cadmium; 12 ppm chromium; 1.5 ppm lead; 70 ppm nickel.	FDA Guidance Documents
Clams, oysters, and mussels	Toxic elements: 86 ppm arsenic; 4 ppm cadmium; 13 ppm chromium; 1.7 ppm lead; 80 ppm nickel.	FDA Guidance Documents
All fish	Methyl mercury—1 ppm.[c]	Sec 540.600 Compliance Policy Guide
All fish	Paralytic shellfish poison—0.8 ppm (80 ∝g/100 g) saxitoxin equivalent.	Sec 540.250 Compliance Policy Guide, and Compliance Program 7303.842
Clams, mussels and oysters, fresh, frozen or canned	Neurotoxic shellfish poison—0.8 ppm (20 mouse units/100 grams) brevetoxin-2 equivalent.	National Shellfish Sanitation Program Manual of Operations
All fish	Amnesic shellfish poison—20 ppm domoic acid, except in the viscera of dungeness crab, where 30 ppm is permitted.	Compliance Program 7303.842
All fish	Hard or sharp foreign object—generally 0.3 (7 mm) to 1.0 (25 mm) in length.	Sec 555.425 Compliance Policy Guide

[a]These values are tolerances;

[b]Sanctioned drugs are approved drugs and drugs used under an INAD;

[c]The term "fish" refers to fresh or saltwater fin fish, crustaceans, other forms of aquatic animal life other than birds or mammals, and all mollusks, as defined in 21 CFR 123.3(d) (FDA, 2005c).

SOURCE: CFSAN, 2001.

C

Tables and Scenarios

BOX C-1
A Case Scenario—The Pregnant Woman[a]

Pregnant women are advised of the potential advantage to their fetuses of EPA/DHA and other nutrients that seafood contains, as well as the potential consequences of exposure to toxicants (both microbiological and environmental). How do pregnant women balance these issues?

A woman establishes her food choices early in life and continues this pattern as she matures (*trajectory*). Pregnancy is a major transition in a woman's life. If this is her first pregnancy, the woman may rely on her family, her partner, medical professionals, and other authorities to provide information upon which to base her food choices (reflecting *cultural influences* and *linked lives*). If she has been pregnant before, she can base her decisions on her previous experience. If new information has been released since her last pregnancy (e.g., a seafood advisory), she may be unaware of the emerging issues (*contextual influences* and *timing in lives*) or she could consider them irrelevant to her own situation. Prior to making her food choices, she may make conscious decisions regarding which foods to eat or to avoid (*adaptive strategies*). For example, a woman who has eaten shrimp as her primary seafood choice throughout her life might consider choosing salmon during her pregnancy. If she was raised on local fish in Wyoming but moved to Michigan at the start of her pregnancy, she might cease to eat any fish (local or otherwise) in response to fish advisories.

[a]Italicized words reflect key concepts of the Life Course Perspective (Wethington, 2005; Devine, 2005).

TABLE C-1 Selected Theoretical Models Describing Health Behavior, Food Choice, and Behavior Change

Theory	Brief Description
Health Belief Model (Rosenstock, 1974)	Assumes individuals will protect their health if they think they are susceptible to the threat, believe that if they change behaviors they can reduce the threat (with benefits outweighing barriers), and that they are able to make the change.
Life Course Perspective (Wethington, 2005)	Key concepts: • trajectories (stable patterns of behavior over time); • transitions (changes in social responsibilies and roles); • turning points (major life events); • cultural and contextual influences (environmental events that shape and constrain change and adaptation); • timing in lives (interaction between the timing of the event and the age/stage of the life course); • linked lives (dependence of one person on another); and • adaptive strategies (conscious decisions)
Optimistic Bias (Shepard, 1999) (Weinstein, 1987)	Underestimation of the risk to oneself relative to others.
PEN-3 (Airhihenbuwa, 1995)	Consists of three interrelated and interdependent dimensions of health: health education diagnosis (identification of the target audience); education diagnosis of health behavior (exploration of target audience's supporting factors and beliefs); and cultural appropriateness of the health behavior (both positive and negative).
Transtheoretical Model (Stages of Change) (Prochaska, 1995) (Prochaska and Vellicer, 1997) (Weinstein et al., 1998)	Integrates a variety of theories (transtheoretical) to both describe progression of changes and to explain associated behaviors necessary to achieve change. Stages include: • *Precontemplation* (time when an individual is not considering or not aware that change is needed); • *Contemplation* (time when an individual is aware of a problem and is considering action to resolve it); • *Preparation* (time when an individual commits to taking action); • *Action* (time when effort is noted); • *Maintenance* (time when a person tries to stabilize the change); • *Termination* (time when no temptation to revert back to old behavior).

TABLE C-2 Processes of Change

Processes	Description
Thinking and Feeling Processes Occurring in *Precontemplation, Contemplation, Preparation, and Maintenance*	
Consciousness raising	Increases information, feedback and understanding about self and problem
Dramatic relief	Expresses and experiences feelings about one's problems and solutions
Self-reevaluation	Assesses one's feelings about oneself with respect to problem
Self-liberation	Consciously chooses and commits to act; believes in ability to change
Social liberation	Increases available alternatives for non-problem societal behaviors
Environmental reevaluation	Assesses how one's problems affect physical condition and social environment
Doing and Reinforcing Processes Occurring in *Preparation, Action, and Maintenance*	
Helping relationships	Is open and trusting about one's problems with someone who cares
Reinforcement management	Rewards self for making changes
Interpersonal systems control	
Counter-conditioning	Substitutes alternatives for problem behavior
Stimulus control	Avoids stimuli that produce problem behavior

SOURCE: Adapted from the *Journal of the American Dietetic Association*, 102 (Supplement 3), Sigman-Grant, Strategies for counseling adolescents, S32–S39, Copyright (2002), with permission from the American Dietetic Association.

BOX C-2
A Family Seafood Selection Scenario

Description of Family Members

Tom: father; 57 years old; his father died of a heart attack at 56 years old
Nan: mother; 55 years old; no family history of cardiovascular disease
Dave: son; 32 years old; healthy, but his BMI is 28
Sharon: daughter; 25 years old; married to Jim and is 2 months pregnant with her first child
Cindy: cousin; 28 years old; lives in Alaska and is visiting Sharon

Context of their lives

Tom, Nan, Dave, Sharon, and Jim live near a lake in the Midwest. They are recreational fishers but tend to catch and release. They usually purchase seafood from the local supermarket.

The family is very health-conscious, and every member goes for yearly check-ups. During Tom's last visit to his cardiologist, the nurse gave him a pamphlet that encouraged him to eat two servings per week of fish high in omega-3 fatty acids.

Nan's gynecologist confirmed that she is in menopause, encouraged her to continue her healthy lifestyle, and suggested she might want to go to the MyPyramid.gov website to get a personalized diet plan using the new Food Guidance System. Since Tom's father died from a heart attack at a young age, Nan has tried to choose lean meat for dinner, including a weekly serving of lean seafood (primarily shrimp). She chooses shrimp because of local advisories warning against eating fatty fish, due to their DLC content. When she goes to her market, she is unable to tell where the fish came from, so she figured shrimp would be the safest.

Dave relies on fast foods. His primary seafood selection, which is a fried fish sandwich, is eaten at least three times a week. Dave was told by his general practitioner to lose weight and he suggested eating lean poultry, meat, and fish.

Sharon and Jim became more thoughtful about their eating patterns when Sharon's pregnancy was confirmed. Before this time, they rarely ate seafood except for canned white tuna which they used occasionally for luncheon sandwiches. On Sharon's first visit to her obstetrician, she told Sharon to increase her intake of DHA and EPA but then Sharon was given a pamphlet that warned her against eating certain fish because they contain methylmercury. Sharon left the office very confused.

Cindy lives in Alaska with her husband's family, who are Inuit. Cindy has acclimated to her new lifestyle with her husband and family. She now eats their traditional diet, including marine seafood. She is planning to get pregnant and is excited to learn what to expect from Sharon.

D

Open Session and Workshop Agendas

**Nutrient Relationships in Seafood:
Selections to Balance Benefits and Risks**

**Institute of Medicine
Food and Nutrition Board**

**National Academy of Sciences
2100 C Street, N.W.
Washington, D.C.**

Tuesday, February 1, 2005

Agenda for Open Session

1:00 p.m. Welcome, Introductions, and Purpose of the Public Session
Malden Nesheim, Committee Chair

Presentations from the Sponsoring Agency:

1:10 US Department of Commerce, National Oceanic and Atmospheric Administration, National Marine Fisheries Service
E. Spencer Garret, Director, National Seafood Inspection Laboratory

2:10 US Department of Health and Human Services, Food and Drug Administration
David W. K. Acheson, Chief Medical Officer and Director, Office of Food Safety, Defense and Outreach

↑↑↑

2:40 US Environmental Protection Agency
Denise Keehner, Director, Standards and health Protection Division, Office of Water

3:10 Break

3:30 Open Discussion

4:00 Adjourn

Nutrient Relationships in Seafood:
Selections to Balance Benefits and Risks

National Academy of Sciences (NAS) Building
Auditorium
2101 Constitution Avenue, N.W.
Washington, D.C.

Monday, April 11, 2005

Preliminary Agenda

8:30 a.m. Welcome and Purpose of the Workshop
Ann Yaktine, Study Director, Food and Nutrition Board, IOM
Malden Nesheim, Chair, Committee on Nutrient Relationships in Seafood

8:45 ***Seafood as a Dietary Component***

Implications of Fatty Acids from Seafood in Chronic Disease and Health
Lawrence Appel, Johnshopkins Bloomberg School of Public health

Contributions of Seafood to the American Diet
Jennifer Weber, Office of Disease Prevention and health Promotion, US Department of health and human Services

Recommendations for Use of Traditional Foods in Alaska
Jim Berner, Alaska Native Tribal Consortium
John Middaugh, Alaska Division of Public health

10:00 Panel Questions

10:15 Break

10:30	***Dietary Practices and Vulnerable Populations***
	Traditional Diets in Native Populations *Don Kashevarof, Alaska Native Tribal Health Consortium*
	Communicating Nutrition Messages to Arctic Communities *Eric Loring, Inuit Tapiriit Kanatami*
	The Economic Impact of Fish Consumption Advisories *Jay Shimshack, Tufts University*
11:45	Panel Questions
Noon	Break for Lunch
1:00 p.m.	***Nutrient Benefits from Seafood***
	Population Studies on Health Benefits Associated with Seafood *Joseph Hibbeln, National Institutes of Health*
	Selenium Modulation of Toxicants in Seafood *Nicholas Ralston, University of North Dakota*
	Dietary Fatty Acids and Immune System Function *Philip Calder, University of Southampton*
2:15	Panel Questions
2:30	Break
2:45	***Mechanisms of Methylmercury Impact on Neurological Outcomes*** *Laurie Chan, McGill University*
	Risk Relationships and Seafood Consumption
	Benefits and Risks of Seafood Selections *Deborah Rice, Maine Bureau of Health*
	Assessing Health Risks Associated with Seafood Contaminants *Louise Ryan, Harvard University*
3:45	Panel Questions
4:00	***Seafood Conservation and Sustainability*** *Mark Dixon, Oregon State University*

4:20 *Interested indiƒiduals and organizations are inƒited to present their ƒiews during this part of the open session. To be considered for a ƒ-minute presentation, please proƒide topic and contact information to Sandra Amamoo-Kakra no later than Marchƒƒƒƒƒƒƒ, ƒ00ƒ, by fax (ƒ0ƒ) ƒƒƒ-ƒƒƒƒ, or by e-mail (samamook@nas.edu).*

4:45 Adjourn

E

Committee Member Biographical Sketches

Malden C. Nesheim, Ph.D. (*Chair*), is Provost Emeritus and Professor of Nutrition Emeritus at Cornell. His previous positions have included Director of the Division of Nutritional Sciences and Vice President for the Planning and Budgeting Program at Cornell University. He has also served as Chair of the Board of Trustees of the Pan American Health and Education Foundation, President of the American Institute of Nutrition, Chair of the National Institutes of Health Nutrition Study Section, and Chair of the National Nutrition Consortium. He also chaired the 1990 US Department of Agriculture/Department of Health and Human Services Dietary Guidelines Advisory Committee and has served as an advisor to the Office of Science and Technology Policy. He is a fellow of the American Society for Nutritional Sciences and of the American Academy of Arts and Sciences. Dr. Nesheim is the recipient of numerous awards including the Conrad A. Elvejhem Award for Distinguished Service to the Public through the Science of Nutrition. His research interests are in human nutrition, nutritional requirements, dietary recommendations, and nutrition policy.

David C. Bellinger, Ph.D., is Professor of Neurology at the Harvard Medical School and Professor in the Department of Environmental Health at the Harvard School of Public Health. He also directs an interdisciplinary postdoctoral training program in Neurodevelopmental Toxicology at the Harvard School of Public Health. Dr. Bellinger has served on the National Research Council's Committee on Evaluation of Children's Health, the Committee on the Toxicological Effects of Mercury, the Committee on Measuring Lead Exposure in Critical Populations, and the Committee on Toxicology Subcommittee on Submarine Escape Action Levels. He has also

served on the FAO/WHO Joint Expert Committee on Food Additives and Contaminants. He was a member of the Federal Advisory Committee of the National Children's Study to examine the effects of environmental influences on the health and development of children. Dr. Bellinger's research interests include early insults to the developing nervous system, exogenous chemical exposures, and endogenous metabolic insults related to serious medical conditions. Much of his research has focused on the neurodevelopmental effects of children's exposures to metals, including lead, mercury, arsenic, and manganese.

Ann Bostrom, Ph.D., is Associate Professor at the School of Public Policy, Georgia Institute of Technology. She is also Associate Dean for Research in the Ivan Allen College, the liberal arts college at Georgia Tech. Dr. Bostrom's research and expertise are in risk perception and communication. Her research focuses on mental models of hazardous processes, including the perception, communication, and management of global environmental change. Dr. Bostrom is currently a member of the US EPA Science Advisory Board Committee on Valuing the Protection of Ecosystems and Ecoservices, and has served on committees for the National Research Council and the Transportation Research Board. In 1997, Dr. Bostrom was awarded the Chauncey Starr Award for a young risk analyst from the Society for Risk Analysis. From 1999–2001, Dr. Bostrom directed the Decision, Risk and Management Science Program at the National Science Foundation. She has previously served on the National Research Council Committee on Optimizing the Characterization and Transportation of Transuranic Waste Destined for the Waste Isolation Pilot Plant, the Committee for the Study of a Motor Vehicle Rollover Rating System, and the Committee for a Study of Consumer Automotive Safety Information.

Susan E. Carlson, Ph.D., is the Midwest Dairy Council Professor of Nutrition at the University of Kansas Medical Center (Kansas City) in the Schools of Allied Health (Dietetics and Nutrition), Medicine (Pediatrics) and Nursing; and Clinical Professor of Obstetrics and Gynecology at the University of Missouri–Kansas City (Kansas City). Her research interests include the nutritional role of long-chain polyunsaturated fatty acids in pregnancy outcome and infant development. In 2002, she was made an honorary member of the American Dietetic Association for her pioneering work in proposing and testing the theory that dietary docosahexaenoic acid (DHA), a component of human milk, is important for the developing human central nervous system. Dr. Carlson is an author on numerous peer-reviewed articles and textbook chapters. She is a charter member of the International Society for the Study of Fatty Acids and Lipids (ISSFAL) and has been an organizer for two international conferences on the role of long-chain polyunsaturated fatty acids for maternal and infant health. She

is also a member of the American Society for Nutrition, American Society for Nutritional Sciences, the American Pediatric Society, and the American Oil Chemists Society. Dr. Carlson reviews widely for journals devoted to publishing research in pediatrics, lipids, and nutrition.

Julie A. Caswell, Ph.D., is Professor and Chairperson in the Department of Resource Economics and Adjunct Professor of Food Science at the University of Massachusetts–Amherst. She served on the Institute of Medicine's Committee on the Implications of Dioxin in the Food Supply. Her research interests include the operation of domestic and international food systems, analyzing food system efficiency, and evaluating government policy as it affects systems operation and performance, in particular the economics of food quality, safety, and nutrition. Her edited book publications include *Economics of Food Safety, Valuing Food Safety and Nutrition*, and *Global Food Trade and Consumer Demand for Quality*. Dr. Caswell has provided her expertise to the UN Food and Agriculture Organization and the Organization for Economic Cooperation and Development on food safety issues. She is a member of the Food Safety Research Consortium. From 1989–2002 she chaired the Regional Research Project NE-165, an international group of over 100 economists who analyzed the operation and performance of the food system. She has also held numerous senior positions with the American Agricultural Economics Association and the Northeastern Agricultural and Resource Economics Association.

Claude Earl Fox, M.D., M.P.H., is Professor in the Department of Epidemiology at the University of Miami and was previously a Professor of Population and Family Health Sciences in the Johns Hopkins Bloomberg School of Public Health. Dr. Fox is also former Director of the Johns Hopkins Urban Health Institute in Baltimore. Prior to this, Dr. Fox was Administrator of the Health Resources and Services Administration of the US Department of Health and Human Services. His research focuses on population and family health and urban health. Dr. Fox served as the co-chair for the Institute of Medicine's Committee on Review of the Use of Scientific Criteria and Performance Standards for Safe Food. He has published widely on family and health issues and improving the nation's health. Dr. Fox is a recipient of the John Atkinson Farroll Prize for Outstanding Contributions to Preventive Medicine and Public Health; the Gay and Lesbian Medical Association Leadership Award; the Special Recognition Award from the National Rural Health Association; the Association of State and Territorial Health Officials Leadership Award; the National Hispanic Medical Association Leadership Award; and others, and he is a member of the Delta Omega Honorary Public Health Society.

Jennifer Hillard is a volunteer with the Consumer Interest Alliance of Canada. From 1996–2002, she served as National Vice President of Issues

and Policy at the Consumer Association of Canada (CAC). She has produced informational booklets in collaboration with the CAC and the Food Biotechnology Communications network. Ms. Hillard also served on the National Research Council/Institute of Medicine's Committee on Identifying and Assessing Unintended Effects of Genetically Engineered Foods on Human Health. She has written many health and safety articles for publications designed for low-literacy consumers.

Susan M. Krebs-Smith, Ph.D., M.P.H., is Chief of the Risk Factor Monitoring and Methods Branch of the Division of Cancer Control and Population Sciences of the National Cancer Institute. She oversees a program of research on the surveillance of risk factors related to cancer—including diet, physical activity, weight status, tobacco use, sun exposure, genetics, and family history; methodological issues to improve the assessment of those factors; and issues related to guidance and food policy. In a previous position at US Department of Agriculture, Dr. Krebs-Smith was a member of the team that developed and tested food guidance recommendations that were subsequently adopted in the *Dietary Guidelines for Americans* and the original Food Guide Pyramid. More recently, she was a member of the drafting committee for the 2005 *Dietary Guidelines*. Her contributions in the area of dietary assessment methodology have focused on reported food intake differences between low energy reporters (LER) and non-LERs, on developing methods to assess dietary patterns, and on estimating usual dietary intake. Dr. Krebs-Smith is a member of the International Advisory Committee, Sixth International Conference on Dietary Assessment Methods, and has served on the editorial boards for both the *Journal of the American Dietetic Association* and the *Journal of Nutrition Education,* and on the Governing Council of the American Public Health Association.

Stanley T. Omaye, Ph.D., is Professor in the Department of Nutrition at the University of Nevada–Reno. Dr. Omaye served as Chief of the Applied Nutrition Branch and as research chemist for the Biochemistry Division, Department of Nutrition at Letterman Army Institute of Research, San Francisco, CA. He also served the US Department of Agriculture as project leader and research chemist at the Western Human Nutrition Center, San Francisco, and project leader and research nutritionist at the Western Regional Research Center, Berkeley. Dr. Omaye is a member of the American College of Nutrition, the Western Pharmacology Society, the American College of Toxicology, the Society of Toxicology, the American Society for Nutritional Sciences, the American Society for Pharmacology and Experimental Therapeutics, and the Institute of Food Technologists. He is author or coauthor of more than 160 publications and serves on the editorial boards of *Toxicology*, *Society of Experimental Biology and Medicine*, and *Nutritional and Environmental Medicine*. Dr. Omaye is a certified nutrition

specialist and a Fellow of the Academy of Toxicological Sciences and of the American College of Nutrition. Dr. Omaye's research efforts are directed at air pollutants, food toxins, selected phytochemicals, tobacco smoke, and aging.

Jose M. Ordovas, Ph.D., is Senior Scientist and Director of the Nutrition and Genomics Laboratory, Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University. Dr. Ordovas' major research interests focus on the genetic factors predisposing to cardiovascular disease and their interaction with the environment and behavioral factors with special emphasis on diet, particularly omega-3 and -6 fatty acids. He has partici - pated in the Framingham Heart Study for nearly 20 years and is carrying out multiple cross-cultural studies to determine cardiovascular risk in different populations around the world, including Asian Pacific and Mediterranean populations. He has written numerous reviews and edited several books on diet and coronary heart disease, diet and genetics, and the role of omega-3 fatty acids on lipoproteins and atherosclerosis. Dr. Ordovas serves on numer ous editorial boards and is active with several American Heart Association and National Institutes of Health committees, including the National Heart, Lung, and Blood Institute Program Projects Parent Committee. Through - out his career, Dr. Ordovas has contributed his expertise to various global organizations. He has served as Nutrition Expert for the American Soybean Association, consulting for Mexico and Central America; was named Expert Consultant to the Singapore Ministry of Health; and is the recipient of the Francisco Grande Memorial Lecture for Excellence in Nutrition.

W. Steven Otwell, Ph.D., is a Professor in the Food Science and Human Nutrition Department of the University of Florida's Institute of Food and Agriculture Sciences. Dr. Otwell is recipient of the Institute of Food Tech - nology's Myron Solberg Award for Excellence and Leadership. Dr. Otwell is the national director of the Seafood Hazard Analysis and Critical Con - trol Points Alliance to help seafood processors and inspectors comply with federal food safety regulations. In 1997, he received Vice President Gore's National Performance Review Award for leadership of the nationwide sea- food safety training program. His research focus is assuring quality, safety, and developments for the seafood industry and general public welfare.

Madeleine Sigman-Grant, Ph.D., R.D., is Professor and Area Specialist at the University of Nevada Cooperative Extension. Dr. Sigman-Grant is nationally known for her work in maternal and early childhood health and nutrition. She received an Early Extension Career Award in 1992 from Epsilon Sigma Phi, a Cooperative Extension honorary fraternity. She served as a member of the Food Advisory Committee for the Food and Drug Administration and is currently a member of the American Academy of Pediatrics panel revising Bright Futures. She is a member of the Society

for Nutrition Education, the American Society of Nutrition, the American Dietetic Association and the International Society for Research in Human Milk and Lactation.

Nicolas Stettler, M.D., MSCE, is Assistant Professor of Pediatrics and Epidemiology at the Children's Hospital of Philadelphia and Senior Scholar at the Center for Clinical Epidemiology and Biostatistics at the University of Pennsylvania School of Medicine. Dr. Stettler is a pediatrician with specialty certification by the American Board of Physician Nutrition Specialists. He is a Fellow of the American Heart Association, the American Academy of Pediatrics, a member of the World Heart Federation, the International Epidemiology Association, and the European and American Societies for Pediatric Research. Dr. Stettler's research interest is in the epidemiology and prevention of obesity and related cardiovascular risk factors in childhood with special emphasis on a life course approach to the development of obesity and related complications.

FNB Liaison

Susan A. Ferenc, D.V.M., Ph.D., is the President of the Chemical Producers and Distributors Association in Alexandria, Virginia. Prior to this position, she served as the Executive Vice President for Scientific and Regulatory Affairs and Chief Science Officer at the Food Products Association, Washington, D.C. Previous experience includes serving as Principal and Senior Consultant, SAF*RISK LC, Madison, Wisconsin; and as Vice President, Scientific and Regulatory Policy, Grocery Manufacturers Association (GMA); Senior Scientist, ILSI Risk Science Institute; and Risk Science Specialist, US Department of Agriculture Office of Risk Assessment and Cost-Benefit Analysis, in Washington, D.C. She also has extensive experience in international field research, having coordinated projects in South America, Africa, and the Caribbean. Areas of expertise include food safety and risk assessment, international program coordination, agricultural policy analysis, food and resource economics, and veterinary medicine and parasitology. Dr. Ferenc belongs to a number of professional societies and has coordinated, chaired, or presented at numerous US and international working groups, expert consultations, and conferences dealing with food safety/risk analysis, etc. She has also published reports, abstracts, books, and presentations dealing with related topics.

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To: Denise Hawkins[**Ex. 6 - Personal Privacy**
From: Wathen, John
Sent: Wed 1/18/2017 6:06:33 PM
Subject: FW: POSTED LIVE: EPA and FDA Fish Advice

Denise-

Hope this finds you well, and happy new year. We finally got this advice done and just in the nick of time. Lisa Larimer and I worked with great folks over at FDA who were willing to stay on track- Deb Smegal, Bill Jones, and our friend Sharon Natanblut. What a process.

Be well,

~John

From: Kearney, Renee
Sent: Wednesday, January 18, 2017 9:28 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
Subject: POSTED LIVE: EPA and FDA Fish Advice

Per your request – DONE

https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish

---

Renee Kearney, Webmaster

202-564-8076 (Office)

202-281-0176 (Work Cell)

Smile to brighten somebody's day

Help to touch somebody's heart

From: Lalley, Cara
Sent: Wednesday, January 18, 2017 8:52 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>; Kearney, Renee <Kearney.Renee@epa.gov>
Subject: FW: Media Relations is sending this release at 9:15 AM: EPA and FDA Issue Final Fish Consumption Advice

Here is the final press release; sorry, but it appears I could not convince them to add a separate web link at the end to EPA's main fish webpage (but readers can get to us via the advice chart and FDA's webpages).

Renee- please start making all of our pages live now. I'll send you the link for the EPA press release when I see it appear in the newsroom.

From: Dennis, Allison
Sent: Wednesday, January 18, 2017 8:48 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Subject: Fwd: Media Relations is sending this release at 9:15 AM: EPA and FDA Issue Final Fish Consumption Advice

Sent from my iPhone

Begin forwarded message:

From: "Valentine, Julia" <Valentine.Julia@epa.gov>

Date: January 18, 2017 at 8:16:34 AM EST
To: AO OPA OMR 60 Minute Warning
<AO_OPA_OMR_60_Minute_Warning@epa.gov>
Cc: "Loop, Travis" <Loop.Travis@epa.gov>, "Dennis, Allison"
<Dennis.Allison@epa.gov>, "Fuld, John" <Fuld.John@epa.gov>
Subject: Media Relations is sending this release at 9:15 AM: EPA and FDA Issue Final Fish Consumption Advice

CONTACTS:

Enesta Jones

EPA

jones.enesta@epa.gov

(202) 236-2426

Theresa Eisenman

FDA

theresa.eisenman@fda.hhs.gov

(301) 796-2969

Consumer Inquiries: 888-INFO-FDA

FOR IMMEDIATE RELEASE
January 18, 2017

EPA and FDA Issue Final Fish Consumption Advice

Chart makes it easier than ever for pregnant women and others to choose from dozens of healthy and safe options; nearly 90 percent of fish eaten in the U.S. fall into "best

choices" category

WASHINGTON - Today, the U.S. Environmental Protection Agency and the U.S. Food and Drug Administration issued final advice regarding fish consumption. This advice is geared toward helping women who are pregnant or may become pregnant – as well as breastfeeding mothers and parents of young children – make informed choices when it comes to fish that are healthy and safe to eat. (This advice refers to fish and shellfish collectively as "fish.")

To help these consumers more easily understand the types of fish to select, the agencies have created an easy-to-use reference chart that sorts 62 types of fish into three categories:

--"Best choices" (eat two to three servings a week)

--"Good choices" (eat one serving a week)

--"Fish to avoid"

Fish in the "best choices" category make up nearly 90 percent of fish eaten in the United States.

An FDA analysis of fish consumption data found that 50 percent of pregnant women surveyed ate fewer than 2 ounces a week, far less than the amount recommended. Because the nutritional benefits of eating fish are important for growth and development during pregnancy and early childhood, the agencies are advising and promoting a minimum level of fish consumption for these groups. The advice recommends 2-3 servings of lower-mercury fish per week, or 8 to 12 ounces. However, all fish contain at least traces of mercury, which can be harmful to the brain and nervous system if a person is exposed to too much of it over time. The maximum level of consumption recommended in the final advice is consistent with the previous recommended level of 12 ounces per week. The new advice is consistent with the 2015 - 2020 Dietary Guidelines for Americans.

For adults, a typical serving is 4 ounces of fish, measured before cooking. Serving sizes for children should be smaller and adjusted for their age and total calorie needs. It is recommended that children eat fish once or twice a week, selected from a variety of fish types.

"Fish are an important source of protein and other nutrients for young children and women who are or may become pregnant, or are breastfeeding. This advice clearly shows the great diversity of fish in the U.S. market that they can consume safely," said FDA Deputy Commissioner for Foods and Veterinary Medicine Stephen Ostroff, M.D. "This new, clear and concrete advice is an excellent tool

for making safe and healthy choices when buying fish." Choices lower in mercury include some of the most commonly eaten fish, such as shrimp, pollock, salmon, canned light tuna, tilapia, catfish and cod.

When updating the advice, the agencies took a cautious and highly protective approach to allow consumers to enjoy the benefits of fish while avoiding those with higher levels of mercury, which is especially important during pregnancy and early childhood. The average mercury content of each type of fish was calculated based on FDA data and information from other sources. The updated advice cautions parents of young children and certain women to avoid seven types of fish that typically have higher mercury levels: tilefish from the Gulf of Mexico; shark; swordfish; orange roughy; bigeye tuna; marlin; and king mackerel.

For fish caught recreationally, consumers are urged to check for local advisories where they are fishing and gauge their fish consumption based on any local and state advisories for those waters. If no information on fishing advisories is available, eat just one fish meal a week from local waters and also, avoid other fish that week. Consumers should clean and trim the fish they catch of fat and skin, since locally-caught fish may contain contaminants besides mercury that can be reduced by proper trimming and cooking, (e.g. broiling instead of frying can reduce some contaminants by letting fat drip away from the fish).

"It's all about eating and enjoying fish of the right kind and in the right amounts," said EPA Director for Water Science and Technology, Elizabeth Southerland, Ph.D. "This joint advice not only provides information for fish consumers who buy from local markets, but it also contains good information for people who catch their own fish or are provided fish caught by friends or relatives."

All retailers, grocers and others are urged to post this new advice, including the reference chart listing fish to choose, prominently in their stores so consumers can make informed decisions when and where they purchase fish. The agencies will be implementing a consumer education campaign working with a wide array of public and private partners featuring the new advice.

In June 2014, the agencies issued draft advice which encouraged pregnant women and others to eat between 8 and 12 ounces of fish a week of fish "lower in mercury" but did not provide a list showing consumers which fish are lower in mercury. The advice issued today also takes into account more than 220 comments received from academia, industry, nongovernmental organizations and consumers as well as an external peer review of the information and method used to categorize the fish.

For More Information:

•□□□□□□□□ Eating Fish: What Pregnant Women and Parents Should Know: http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm393070.htm

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

The EPA, a federal agency, works to protect all Americans from significant risks to human health and the environment where they live, learn and work. The agency focuses on all parts of society, from individuals to businesses and local governments. It develops regulations concerning natural resources, energy, transportation, agriculture, and industry and supports the various facets of environmental research and protection.

R017

Julia P. Valentine

Acting Director

Office of Media Relations

US EPA Headquarters

202.564.2663 desk

202.740.1336 m/txt

To: Ex. 6 - Personal Privacy
From: Wathen, John
Sent: Wed 1/18/2017 3:18:28 PM
Subject: FW: POSTED LIVE: EPA and FDA Fish Advice

Elsie-

You may have inferred what I was up to when I sought your assistance a time or two, but I thought you would appreciate seeing our final output on this. Your work on describing sources of exposure was highly influential here and I think I have mentioned appreciating you Pacific modeling and description of water-column Hg methylation.

Thanks!

~John

https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish

FOR IMMEDIATE RELEASE
January 18, 2017

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Chart makes it easier than ever for pregnant women and others to choose from dozens of healthy and safe options; nearly 90 percent of fish eaten in the U.S. fall into "best choices" category

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R017

To: Wathen, Samuel Ex. 6 - Personal Privacy
From: Wathen, John
Sent: Wed 1/18/2017 2:58:16 PM
Subject: RE: POSTED LIVE: EPA and FDA Fish Advice

That's for women who might become pregnant. You're OK for bigeye once a month, but you could eat fish more often selecting from the other categories. Cardiac effects of Hg are not well defined, but it's not good for anyone. You know I've developed an allergy to raw/ undercooked (Ahi) tuna.

Yes, we are ready for Donald. We work for whoever is in the house, we just hope we don't get whipped too bad.

~AF

From: Wathen, Samuel Ex. 6 - Personal Privacy
Sent: Wednesday, January 18, 2017 9:45 AM
To: Wathen, John <Wathen.John@epa.gov>
Subject: RE: POSTED LIVE: EPA and FDA Fish Advice

In pains me to see bigeye tuna in the no no category..

Ready for Don down there?

From: Wathen, John Ex. 6 - Personal Privacy
Sent: Wednesday, January 18, 2017 9:42 AM
To: Axie N.; Frederick Sheehan; Wathen, Samuel (KBW-New York 7th Ave); Ex. 6 - Personal Privacy Diane Wathen; Dick Wathen; John Wathen
Subject: FW: POSTED LIVE: EPA and FDA Fish Advice

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To: Lalley, Cara <Lalley.Cara@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>; Christensen, Christina <Christensen.Christina@epa.gov>
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https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish

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Renee Kearney, Webmaster

202-564-8076 (Office)

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> **CONTACTS:**
>
> Enesta Jones
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> EPA
>
> jones.enesta@epa.gov
>
> (202) 236-2426

Theresa Eisenman

FDA

theresa.eisenman@fda.hhs.gov

(301) 796-2969

Consumer Inquiries: 888-INFO-FDA

FOR IMMEDIATE RELEASE
January 18, 2017

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R017

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Acting Director

Office of Media Relations

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202.564.2663 desk

202.740.1336 m/txt

To: Axie N [redacted]; Frederick Sheehan [redacted]; Wathen, Samuel [redacted]; [redacted]; Diane Wathen [redacted] Dick Wathen [redacted] John Wathen [redacted]
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Fish Consumption Advice

CONTACTS:

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From: Wathen, John
Sent: Tue 1/17/2017 9:45:12 PM
Subject: RE: Advice Call info for Betsy for 1/18

Confirming commerce in the AM?

~John

From: Barash, Shari
Sent: Tuesday, January 17, 2017 4:38 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Wathen, John <Wathen.John@epa.gov>
Subject: Re: Advice Call info for Betsy for 1/18

Lisa,

I will send to Betsy and cc you both. I think I want to do it from a computer so she doesn't end up with the older attachment.

Shari

Sent from my iPhone

On Jan 17, 2017, at 3:45 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

> I found it a little disjointed, so I cleaned up the attachment a little. Also fixed some typos in the email:
>
> Betsy-
>
> The webpages go live at 8:45 AM on Wed. 1/18/17. The press release is posted at 9:15 AM.

We have two calls for you to make at 9:15 AM:

Ex. 5 - Deliberative Process

Attachment shows which entities EPA is contacting (p. 1), suggested talking points (p. 2), and list of entities FDA is contacting (p. 3).

Shari, Sara, Lisa, and John

From: Wathen, John
Sent: Tuesday, January 17, 2017 3:07 PM
To: Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: Advice Call info for Betsy for 1/18

Betsy-

The webpages go live at 8:45 AM 1/18/17. The press release is post 9:15 AM

They (FDA) have two calls for you to make:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Suggest talking points are included in the attached, as well as the list of entities FDA is calling.

Shari, Sara, Lisa, and John

John Wathen

Senior Science Advisor, Fish and Beach Programs

National Branch (4305 T)

<'}}}>< _/)~~~ <'}}}>< _/)~~~ <'}}}><

Standards and Health Protection Division

Office of Science and Technology

Office of Water

US Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, DC 20460

202-566-0367 phone

202-566-0409 fax

http://www.epa.gov/waterscience

<Fish advice rollout info & TPs 1-17-17.docx>

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Smegal, Deborah[Deborah.Smegal@fda.hhs.gov]; Jones, William[William.Jones@fda.hhs.gov]
From: Wathen, John
Sent: Tue 1/17/2017 9:43:03 PM
Subject: RE: chart graphic on web page

We'll both be in the office. I thin Betsy S. is working this from home. We are getting closed in around here.

~John

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, January 17, 2017 4:33 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Jones, William <William.Jones@fda.hhs.gov>
Subject: RE: chart graphic on web page

Lisa, are you guys all set for tomorrow? Let's stay in close touch in the morning via email, okay? Hopefully the FR notice will post around 8:45, FDA and EPA will post around 9:15, Betsy will make her calls, we'll make our calls, and we'll see what the media coverage is, what the stakeholder reaction is, and what we need to do next!

And then – and this is most important – we plan a celebration for the four of us at a great seafood restaurant!!!

Sharon

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, January 17, 2017 4:23 PM
To: Abi-Khattar, Cathy; Natanblut, Sharon
Cc: Smegal, Deborah; CFSAN-Webmaster
Subject: RE: chart graphic on web page

Thank you! If anything does change, please loop in my webmaster at Kearney.renee@epa.gov

From: Abi-Khattar, Cathy [mailto:Cathy.Abi-Khattar@fda.hhs.gov]
Sent: Tuesday, January 17, 2017 4:14 PM
To: Larimer, Lisa <Larimer.Lisa@epa.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>
Subject: RE: chart graphic on web page

Here is the current version of everything. Below are the links that each piece will have when we are live tomorrow. Hope that helps.

Please note, if any of the attached change again this evening, I will resend the new versions to you.

Thanks

Cathy

QA English page
http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm534873.htm

QA English PDF
http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM537120.pdf

QA Spanish page
http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm537141.htm

QA Spanish PDF
http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM537166.pdf

FDA and EPA's Response to External Peer Review on the FDA-EPA's Technical Information on the Development
http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessm

External Peer Review Report: FDA-EPA's Technical Information on Development of Fish Consumption Advice (this is the report done by contractors)
http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessm

Cathy Abi-Khattar

CFSAN Web Team

5001 Campus Dr

College Park, MD 20740

240-402-1906

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, January 17, 2017 3:21 PM
To: Natanblut, Sharon; Abi-Khattar, Cathy
Cc: Smegal, Deborah
Subject: RE: chart graphic on web page

I suppose we can link to yours, but I'll need the direct link for each document.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Tuesday, January 17, 2017 3:08 PM
To: Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: chart graphic on web page

That was my understanding but we need Lisa to confirm.

From: Abi-Khattar, Cathy
Sent: Tuesday, January 17, 2017 3:08 PM
To: Larimer, Lisa; Natanblut, Sharon
Cc: Smegal, Deborah

Subject: Re: chart graphic on web page

The images I sent is what I have.

For the other pieces, I was under the impression EPA is linking to our pieces. Sharon can you confirm? I can send the pieces if EPA is posting separate copies.

Thanks!

Cathy Abi-Khattar
CFSAN Web Branch

From: Larimer, Lisa

Sent: Tuesday, January 17, 2017 3:03 PM

To: Abi-Khattar, Cathy; Natanblut, Sharon

Cc: Smegal, Deborah

Subject: RE: chart graphic on web page

Thanks. I tried exporting a jpg of the full chart from the pdf, but it didn't come out clearly. Do you have a better version?

In addition, my webmaster is asking for (508-compliant) pdfs of the following, which I don't have:

- Q&A in English
- Q&A in Spanish
- Summary of public comments and agency responses
- Peer review report

I'm hoping you have them?

From: Abi-Khattar, Cathy [mailto:Cathy.Abi-Khattar@fda.hhs.gov]
Sent: Tuesday, January 17, 2017 12:37 PM
To: Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>
Subject: RE: chart graphic on web page

Here is the image of the fish advice PDF and the image we are using for social media.

Our website development works differently so not sure how their side is going to code the same look and feel that we went with. Attached is a screenshot of how our page will look.

Thanks

Cathy

Cathy Abi-Khattar

CFSAN Web Team

5001 Campus Dr

College Park, MD 20740

240-402-1906

From: Natanblut, Sharon
Sent: Tuesday, January 17, 2017 12:35 PM
To: Abi-Khattar, Cathy; Larimer, Lisa
Subject: RE: chart graphic on web page

Do you want to send both? I'm not sure either! Also, do they have what's going on our landing page?

From: Abi-Khattar, Cathy
Sent: Tuesday, January 17, 2017 12:34 PM
To: Natanblut, Sharon; Larimer, Lisa
Subject: RE: chart graphic on web page

I am not sure what exactly we need to send. The social media image or just an image of the PDF?

Cathy Abi-Khattar

CFSAN Web Team

5001 Campus Dr

College Park, MD 20740

240-402-1906

From: Natanblut, Sharon
Sent: Tuesday, January 17, 2017 12:31 PM
To: Larimer, Lisa; Abi-Khattar, Cathy
Subject: RE: chart graphic on web page

Cathy, did you get back to Lisa on this? I'd love if we gave them everything we have if that's possible. Thanks.

From: Larimer, Lisa [mailto:Larimer.Lisa@epa.gov]
Sent: Tuesday, January 17, 2017 10:15 AM
To: Natanblut, Sharon; Abi-Khattar, Cathy
Subject: chart graphic on web page

I think I mentioned that I really liked your idea of having the chart as a graphic on the web page. Since you've already converted it into graphic form, can I send that to my webmaster so she doesn't have to duplicate work that already been done?

Thanks!

Lisa

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Tue 1/17/2017 1:54:59 PM
Subject: RE: Spanish translation of Fish Advice Qs and As

Bueno. Muchas gracias.

~Juanito

From: Larimer, Lisa
Sent: Monday, January 16, 2017 9:40 PM
To: CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>
Cc: Jones, William <William.Jones@fda.hhs.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Spanish translation of Fish Advice Qs and As

Cathy, here is the Spanish translation of the QA.

-Lisa

To: jwath Ex. 6 - Personal Privacy
From: Wathen, John
Sent: Fri 12/18/2015 2:16:04 PM
Subject: Fw: Administrator McCarthy cc'ed on Letter to Dr. Ostroff re: Seafood Advice
121715 Seafood Advice Letter to FDA.pdf

From: Hisel-Mccoy, Sara
Sent: Thursday, December 17, 2015 4:14 PM
To: Larimer, Lisa; Wathen, John; Barash, Shari
Subject: FW: Administrator McCarthy cc'ed on Letter to Dr. Ostroff re: Seafood Advice

FYI

From: Borum, Denis
Sent: Thursday, December 17, 2015 2:57 PM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>; Beauvais, Joel <Beauvais.Joel@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Peck, Gregory <Peck.Gregory@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Orvin, Chris <Orvin.Chris@epa.gov>
Subject: Administrator McCarthy cc'ed on Letter to Dr. Ostroff re: Seafood Advice

All,

Please see attached letter from Senators Murray plus 29, regarding FDA advice on seafood consumption for pregnant women. The letter is addressed to Dr. Ostroff at FDA, but Gina McCarthy is cc:ed. Just an FYI for us. I had brought this up a week ago at the OW Weekly management meeting re: Senate EPW minority inquiry. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Denis

Denis R. Borum

Congressional Liaison Specialist

Office of Congressional and Intergovernmental Relations

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, N.W. (MC-1301A)

Washington, D.C. 20460

(202) 564-4836 (phone)

(202) 501-1549 (fax)

borum.denis@epa.gov (e-mail)

From: Wathen, John
Location: CFSAN CP Room 2A023
Importance: Normal
Subject: Accepted: FDA/EPA fish advice meeting
Start Date/Time: Mon 12/14/2015 7:00:00 PM
End Date/Time: Mon 12/14/2015 10:00:00 PM

From: Wathen, John
Location: DCRoomWest5231L/DC-CCW-OST
Importance: Normal
Subject: Accepted: discuss fish advice
Start Date/Time: Wed 12/9/2015 7:00:00 PM
End Date/Time: Wed 12/9/2015 8:00:00 PM

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Fri 11/20/2015 2:55:31 PM
Subject: Re: Updated & shortened options for fish advice

I see the issue. I have suffered from fat fingers all my life.

~John

From: Larimer, Lisa
Sent: Friday, November 20, 2015 9:37 AM
To: Wathen, John
Subject: FW: Updated & shortened options for fish advice

Here you go. Sorry you didn't get it. I need a new keyboard. I can't read any of the keys and I'm constantly mistyping n and m.

From: Larimer, Lisa
Sent: Thursday, November 19, 2015 11:07 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari Barash.Shari@epa.gov; John Wathem
Subject: Updated & shortened options for fish advice
Importance: High

Betsy-

It occurred to me this morning that since Joel has just recently gotten involved in the fish advice, he may not know that **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

I took the information I pulled together for last week's meeting with Joel and made some changes:

- □□□□□□□ boiled it down to one page of clear options
- □□□□□□□ added a few things I mentioned verbally at last week's meeting like Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

I'm not sure if you'll have time to look at it and get it to Joel before his meeting at 2:00 today, but I thought it was worth a shot.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
From: Wathen, John
Sent: Fri 11/20/2015 2:32:01 PM
Subject: Fw: Fish Advice

Lisa-

I am frustrated that I do not have the email to which joel is referring.PLease be so kind as to forward.

~John

From: Beauvais, Joel
Sent: Friday, November 20, 2015 7:34 AM
To: Southerland, Elizabeth
Cc: Behl, Betsy; Larimer, Lisa; Hisel-Mccoy, Sara; Barash, Shari; Wathen, John
Subject: Re: Fish Advice

Thank you - apologies for the confusion on the DD and thanks for clarifying.

On Nov 20, 2015, at 6:51 AM, Southerland, Elizabeth <Southerland.Elizabeth@epa.gov> wrote:

> Thanks, Joel, for helping us through this. I am copying the other fish advice team members because I don't know who is in the office today. Sara Hisel-McCoy is the DD involved, not Betsy Behl.
>
> Sent from my iPhone
>
> On Nov 19, 2015, at 9:28 PM, Beauvais, Joel <Beauvais.Joel@epa.gov> wrote:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Thanks for your help on this.

Joel

To: Fisher, Jacqueline[Fisher.Jacqueline@epa.gov]
Cc: Murphy, Elizabeth[Murphy.Elizabeth@epa.gov]
From: Wathen, John
Sent: Mon 11/16/2015 6:29:26 PM
Subject: CLOSE HOLD
FISH_CHART_15-10-15.pdf
Fish Advice Qs and As-10 15 15clean.docx
technical web page-fish advice- 10 15 15clean.docx

Draft FDA –EPA advice documents as requested. Keep them to yourselves, please. This is very sensitive- interagency, congressional, very sensitive.

~John

John Wathen

Senior Scientist, Fish and Beach Programs

National Standards Branch (4305 T)

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Standards and Health Protection Division

Office of Science and Technology

Office of Water

US Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, DC 20460

202-566-0367 phone

202-566-0409 fax

http://www.epa.gov/waterscience

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Wathen, John
Sent: Fri 11/13/2015 3:06:26 PM
Subject: Re: Call tomorrow

I think I make Burke mad.

~John

From: Southerland, Elizabeth
Sent: Thursday, November 12, 2015 5:17 PM
To: Wathen, John
Cc: Hisel-Mccoy, Sara; Larimer, Lisa; Barash, Shari; Martin, Jeanette
Subject: Re: Call tomorrow

Joel is restricting attendance to just me on the phone and Lisa in person. I have no idea why but am following his instructions.

Sent from my iPhone

On Nov 12, 2015, at 4:49 PM, Wathen, John <Wathen.John@epa.gov> wrote:

> Betsy-
>
> Am I correct in assuming we will be receiving a call-in number for the call tomorrow?
>
> ~John

From: Southerland, Elizabeth
Sent: Thursday, November 12, 2015 3:41 PM
To: Hisel-Mccoy, Sara
Cc: Larimer, Lisa; Barash, Shari; Wathen, John
Subject: Re: Info for Joel on fish advice

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Sent from my iPhone

On Nov 12, 2015, at 3:21 PM, Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov> wrote:

Betsy – I am reading now but I thought it would save time if I just forwarded directly. I don't have a sense of what would be too long for Joel. Do you? Sara

From: Larimer, Lisa
Sent: Thursday, November 12, 2015 3:15 PM
To: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Info for Joel on fish advice

Here you go! I hope it's not too long, but if this is our one shot, I didn't want to skimp too much.

Pasting into the email, in case you're on Blackberry. May be tough to read that way, though:

Fish Advice – Additional Information

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

<Fish advice-info for Joel Beauvais.docx>

To: Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Wathen, John
Sent: Fri 1/23/2015 4:07:53 PM
Subject: Fw: What are the next steps on FDA-EPA Fish Advisory?

That Betsy is a pistol. I provided the bullets below to Sara who highlighted the first three to Betsy as most time- relevant. Betsy grabbed the whole handful and blazed away. We'll see what happens.

~John

From: Southerland, Elizabeth
Sent: Friday, January 23, 2015 10:49 AM
To: Natanblut, Sharon
Cc: Hisel-Mccoy, Sara; Elkin, Ted; Wathen, John
Subject: RE: What are the next steps on FDA-EPA Fish Advisory?

I would like a call! I am free at 9 AM on Wednesday and 11 to 3 PM on Thursday. Hopefully, you will have time in one of those slots to discuss with me, Sara, and John.

From: Natanblut, Sharon [mailto:Sharon.Natanblut@fda.hhs.gov]
Sent: Friday, January 23, 2015 10:39 AM
To: Southerland, Elizabeth
Cc: Hisel-Mccoy, Sara; Elkin, Ted
Subject: RE: What are the next steps on FDA-EPA Fish Advisory?

Hi Betsy,

Good to hear from you. Yes, lots of changes with both Denise and Phil retiring.

I think it would be great to have a call, and I'd like Ted Elkin, our CFSAN acting deputy director to join if possible. We are going through a lot of transition here because not only did Phil retire but so did Mike Landa, the CFSAN center director. Our new director, Dr. Susan Mayne, is starting MONDAY!! As you can imagine, she'll need a little time to get up to speed.

That said, we are in the process of determining who will be the CFSAN point person in place of Phil. I will continue to be involved from the Deputy Commissioner's office. The FR notice is going through clearance now and I hope it can post in February. You've seen the version that was placed in clearance and the only changes I've seen have been very minor. I will of course send it to you once we've got a cleared version.

In terms of the process/scope of response to the comments, and the schedule for revising and collaborating on revisions to the advisory are all things that we really want to sit down and discuss that with you and decide jointly what would be most appropriate. I was seeing this as a real partnership. The RCAC has completed its job and nothing further will be posted other than the summary notes and transcript.

For your last question, my hope is that we can work together to promote the revised advice as extensively as possible. Our education team is eager to work with you on this.

Should we follow-up by phone next week to discuss these issues more fully?

Thanks.

Sharon

From: Southerland, Elizabeth [mailto:Southerland.Elizabeth@epa.gov]
Sent: Friday, January 23, 2015 8:01 AM
To: Natanblut, Sharon
Cc: Hisel-Mccoy, Sara
Subject: What are the next steps on FDA-EPA Fish Advisory?

Sharon, I just heard that Phil Spiller retired. Is that true? Our branch chief responsible for fish contamination, Denise Hawkins, also retired this month. We need to discuss the path forward to finalize the advisory, especially since we will both be short of staff. I have the following questions which need to be answered before we figure out next steps. Can you provide answers or do we need to arrange a call/meeting to discuss? Just let me know. Hope you are doing well!

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Bigler, Jeff[Bigler.Jeff@epa.gov]
From: Wathen, John
Sent: Thur 11/6/2014 1:10:29 PM
Subject: FW: My presentation from Monday
Groth critique.pptx

From: Ned Groth [mailto:nedgroth@cs.com]
Sent: Wednesday, November 05, 2014 4:28 PM
To: Wathen, John
Subject: My presentation from Monday

Dear John,

Great seeing you again and next time I will attach a name to the face!

Here is my Powerpoint from Monday, as you requested. I also submitted long written comments that make many of the same points with much greater detail. Let me know if you want that too.

Best regards,

Ned Groth
nedgroth@cs.com

From: Means-Thomas, Janet
Location: Kevin can call 202 564-6620
Importance: Normal
Subject: Copy: Phone call on Fish Advice Burke/Rennert
Start Date/Time: Thur 10/8/2015 6:00:00 PM
End Date/Time: Thur 10/8/2015 6:30:00 PM

From: Meiburg, Stan
Location: DCRoomARN3530CFTB/DC-Ariel-Rios-AO
Importance: Normal
Subject: Copy: FDA-EPA Fish Advice
Start Date/Time: Tue 9/22/2015 3:00:00 PM
End Date/Time: Tue 9/22/2015 3:45:00 PM
Briefing Memo FDA-EPA fish advice.docx

Point of Contact for the Meeting: Lisa Larimer 566-1017
SCt: Denise Anderson, 564-1782

Call In # **Ex. 6 - Personal Privacy**

Purpose:	Share the final joint FDA-EPA fish advice with EPA senior leadership. HHS senior leadership is receiving a comparable briefing. The workgroup's goal is to announce the advice in September/October 2015, contingent upon timing of review by HHS and OMB.
Background:	An FDA-EPA workgroup has developed an update to the March 2004 fish advisory on mercury in fish and shellfish. The advice recommends consumption frequencies for the target audience of pregnant and breastfeeding women, women who could become pregnant, and children.

Last possible date for the meeting: After 9/9/15 and before 9/25/15

EPA Staff (Required):	OW: Lisa Larimer, John Wathen, Sara Hisel-McCoy, Elizabeth Southerland, Ken Kopocis, Ellen Gilinsky ORD: Thomas Burke OA: Ruth Etzel, Theodore Coopwood OGC: Stacey Mitchell, Lee Schroer
EPA Staff (Optional):	OW: Travis Loop, Cara Lalley ORD: Robert Kavlock, Fred Hauchman, Rita Schoeny OA: Khesha Reed, Michael Firestone

To: Adm13McCarthy, Gina[Adm13McCarthy.Gina@epa.gov]; Meiburg, Stan[Meiburg.Stan@epa.gov]; Fritz, Matthew[Fritz.Matthew@epa.gov]; Reynolds, Thomas[Reynolds.Thomas@epa.gov]; Beauvais, Joel[Beauvais.Joel@epa.gov]; Vaught, Laura[Vaught.Laura@epa.gov]; Pieh, Luseni[Pieh.Luseni@epa.gov]; Rupp, Mark[Rupp.Mark@epa.gov]; Garbow, Avi[Garbow.Avi@epa.gov]; Bond, Brian[Bond.Brian@epa.gov]; Garvin, Shawn[garvin.shawn@epa.gov]; Stanislaus, Mathy[Stanislaus.Mathy@epa.gov]
Cc: Kadeli, Lek[Kadeli.Lek@epa.gov]; Kavlock, Robert[Kavlock.Robert@epa.gov]; Blackburn, Elizabeth[Blackburn.Elizabeth@epa.gov]; Smith, Kelley[Smith.Kelley@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]; Hubbard, Carolyn[Hubbard.Carolyn@epa.gov]; Naples, Eileen[Naples.Eileen@epa.gov]
From: Burke, Thomas
Sent: Sun 8/9/2015 3:57:04 PM
Subject: ORD/OSA Weekly Report

Administrator,

I am pleased to present the ORD/OSA weekly report.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Mercury in Fish Advisory

At OW's request, ORD reviewed the draft fish advisory for mercury and supporting materials that OW intends to release to the public in September 2015. ORD has not identified any scientific issues with the advisory and commends OW for their final product, which reflects lengthy negotiations with FDA.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Burke, Thomas[Burke.Thomas@epa.gov]
Cc: Kadeli, Lek[Kadeli.Lek@epa.gov]; Kavlock, Robert[Kavlock.Robert@epa.gov]; Blackburn, Elizabeth[Blackburn.Elizabeth@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]; Smith, Kelley[Smith.Kelley@epa.gov]; Maguire, Megan[Maguire.Megan@epa.gov]; Gibbons, Dayna[Gibbons.Dayna@epa.gov]; Gwinn, Maureen[gwinn.maureen@epa.gov]; Corona, Elizabeth[Corona.Elizabeth@epa.gov]
From: Hubbard, Carolyn
Sent: Fri 8/7/2015 8:42:57 PM
Subject: Draft ORD/OSA Weekly Week of August 10

Hi Tom- here's the weekly. Talk to you next week,

Carolyn

Adm13McCarthy.Gina@epa.gov

Meiburg.Stan@epa.gov

Reynolds.Thomas@epa.gov

Beauvais.Joel@epa.gov

Fritz.Matthew@epa.gov

Vaught.Laura@epa.gov

Pieh.Luseni@epa.gov
Rupp.Mark@epa.gov

Garbow.avi@epa.gov

Bond.brian@epa.gov
Garvin.Shawn@epa.gov

CC:
Kavlock.Robert@epa.gov
Blackburn.Elizabeth@epa.gov
Smith.Kelley@epa.gov
Kadeli.Lek@epa.gov
Hubbard.Carolyn@epa.gov

Kim.hyon@epa.gov

Naples.eileen@epa.gov

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

ORD and OAR attended this planning meeting on August 5th. The US and China have been collaborating on cook stoves research through EPA's work with China's Ministry of Science and Technology (MOST) as part of this broader government initiative and our commitments to the Global Alliance for Clean Cook stoves. There is an opportunity at the ESM meeting to continue to spread our messages about our ongoing work on cook stoves and to further explore a parallel extramural research solicitation on energy use for heating, cooking and lighting with MOST.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Mercury Fish Advisory

At OW's request, ORD reviewed the draft fish advisory for mercury and supporting materials that OW intends to release to the public in September 2015. ORD has not identified any scientific issues with the advisory and commends OW for their final product, which reflects lengthy negotiations with FDA.

Ex. 5 - Deliberative Process

To: Adm13McCarthy, Gina[Adm13McCarthy.Gina@epa.gov]; Meiburg, Stan[Meiburg.Stan@epa.gov]; Fritz, Matthew[Fritz.Matthew@epa.gov]; Reynolds, Thomas[Reynolds.Thomas@epa.gov]; Beauvais, Joel[Beauvais.Joel@epa.gov]; Vaught, Laura[Vaught.Laura@epa.gov]; Rupp, Mark[Rupp.Mark@epa.gov]; Pieh, Luseni[Pieh.Luseni@epa.gov]; Garbow, Avi[Garbow.Avi@epa.gov]; Garvin, Shawn[garvin.shawn@epa.gov]
Cc: Kadeli, Lek[Kadeli.Lek@epa.gov]; Kavlock, Robert[Kavlock.Robert@epa.gov]; Blackburn, Elizabeth[Blackburn.Elizabeth@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]; Smith, Kelley[Smith.Kelley@epa.gov]; Hubbard, Carolyn[Hubbard.Carolyn@epa.gov]; Naples, Eileen[Naples.Eileen@epa.gov]
From: Burke, Thomas
Sent: Sun 10/4/2015 4:39:57 PM
Subject: ORD/OSA Weekly Report

Administrator,

I am pleased to submit our ORD/OSA Weekly Report. This week ORD will continue to work with Region 5, providing technical assistance to Michigan as the state works to address concerns about drinking water quality in Flint. We will also be meeting with OW and others as we consider the proposed joint EPA/FDA fish consumption advice. In addition, on Monday I will participate in the White House National Science and Technology Council Committee on Science. The agenda will include an update on the Open Data Policy implementation.

Gold King Mine Response

Ex. 5 - Deliberative Process

Laboratory Enterprise Forum

I look forward to the first meeting of the Forum, established within the Science and Technology Policy Council to promote effective communication, coordination, and collaboration across the Agency's laboratory enterprise. ORD's Bill Benson has been chosen to serve as Chair. Beginning with its first meeting on October 7 the LEF will develop recommendations for the effective and efficient management of the Agency's laboratory enterprise.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Village Green Station Operational in Oklahoma City

Village Green's newest station is now operating in downtown Oklahoma City, OK in the Myriad Botanical Gardens. ORD is coordinating with Region 6 and the Oklahoma Department of Environmental Quality to plan a community event on in November to promote the bench.

Last Week

White House OSTP Forum on Open Science and Innovation

Dr. John Holdren released a memo at the OSTP forum partially organized by ORD providing recommendations to federal agencies on how to best tap in to these open science and innovation tools. GSA also committed to building a government-wide online database of citizen science projects for the public. R1's Deb Szaro facilitated an exciting session on how citizen science and crowdsourcing can empower communities citing EPA's great work in the Ironbound community, in the Charles River and on harmful algal blooms. There was an good energy at this meeting.

Launch of Federal Crowdsourcing and Citizen Science Toolkit

We are also pleased that last week OSTP released the public version

of the toolkit which provides step-by-step guides for federal employees on how to run citizen science and crowdsourcing projects. ORD played a substantial role in compiling the content of this site. This was a collaborative effort led by the Federal Community of Practice on Crowdsourcing and Citizen Science – co-chaired by EPA and NASA. This will be a valuable tool for EPA researchers to support their work and to empower communities. Several existing federal efforts were highlighted in the OSTP toolkit as case studies of best practices including the EPA Air Sensors Toolbox. Many EPA staff have made valuable contributions to this effort.

Federal Register Notice issued for Generic Information Collection Request

On October 1st, EPA published a Federal Register Notice for a generic information collection request for crowdsourcing and citizen science. ORD worked with OGC and OEI on this in coordination with OMB. An expedited process for OMB approval of citizen science projects would help EPA researchers. It may be possible to reduce the time of processing an information collection request from 9 months to just a few weeks.

ORD Grantee Named MacArthur Fellow

On September 29, Dr. Kartik Chandran was named as a 2015 MacArthur Fellow for his research efforts to transform wastewater from a pollutant into a sustainable resource, such as alternative energy sources, chemicals or fertilizers. This includes a "genius grant" of $625,000. Dr. Chandran is an Associate Professor of earth and environmental engineering at Columbia University. Key insights from his research demonstrate that certain combinations of mixed microbial communities, similar to those naturally-occurring, can be used to mitigate the harmful environmental impacts of wastewater and extract useful products. Dr. Chandran has received numerous EPA grants for his research. Currently, he is a co-Principal Investigator for a grant to the Water Environment Research Foundation, *National Center for Resource Recovery and Nutrient Management*. This Center will

develop and test new methods for nutrient reduction through resource recovery and human behavior. He is also a former P3-People, Prosperity, and the Planet, award recipient, *Development of Source-Separation Latrine Technology for Sustainable Human Waste Management in Rural Ghana*.

European Union Rendez-Vous

On September 29, a special Rendez-Vous on environmental sustainability was held at the EU's Delegation Offices in Washington, D.C. This event was jointly organized by the World Resources Institute, EPA and the European Environment Agency. The event marked Karmen Vella, the European Commissioner for Environment, Maritime Affairs and Fisheries' first official visit to Washington, D.C.. The session was facilitated by Andrew Steer, WRI President, and included Commissioner Vella, Jane Nishida, and Hans Bruyninckx, head of the European Environment Agency. ORD's Michael Slimak and Hans Bruyninckx discussed the EU's State of the Environment Report and EPA's Report on the Environment. Earlier in the day, Hans Bruyninckx presented an Agency-wide webinar on the EU's focus on sustainability and future directions of sustainability development goals.

RETIGO

On September 29th, 80 attendees from within and outside EPA participated in-person and via webinar as ORD and Region 2 presented the "Real-Time Geospatial Data Viewer (RETIGO): An EPA-Developed Web-based Tool for Researchers and Citizen Scientists to Explore their Air Measurements." This Google Maps-linked tool allows users with portable instruments to upload environmental data measured across time and space and explore that data interactively. Region 2 has played a critical advising role in the development of RETIGO 2.0, resulting in new options for users such as data visualization for stationary devices and collaborative data uploading for community groups.

ORD Senior Scientist Interviewed for New York Times at Blouin Creative Leadership Summit (BCLS) in New York, NY City

A New York Times story covering sustainability was published on September 25. The article, "A Day for an Ecology-Minded Pope and Sustainable Development Goals," was written by Andrew C. Revkin, the moderator for a panel at the Summit. ORD's Heriberto Cabezas was an invited participant on the panel and is quoted in the article.

To: Deener, Kathleen[Deener.Kathleen@epa.gov]; Smith, Kelley[Smith.Kelley@epa.gov]
From: Schoeny, Rita
Sent: Mon 9/21/2015 8:20:28 PM
Subject: FW: Materials for FDA-EPA Fish Advice briefing
FISH_CHART_V_9.2.pdf
FISH_CHART_H_9.2.pdf
FDA-EPA Fish Advice briefing for DA.pptx

Hi. Would you please see that Tom has these. Thanks.

Rita Schoeny, Ph.D.
Senior Science Advisor, Office of Science Policy
Office of Research and Development
U.S. Environmental Protection Agency
Room 51134 RRB
1200 Pennsylvania Avenue NW (8104R)
Washington DC 20460-0001

202-566-1127
202-565-2911 fax

Address for delivery:
1300 Pennsylvania Ave. NW
Room# 51134 MC8104R
Washington DC 20004

From: Larimer, Lisa
Sent: Monday, September 21, 2015 4:08 PM
To: Wathen, John; Hisel-Mccoy, Sara; Southerland, Elizabeth; Burke, Thomas; Etzel, Ruth; Coopwood, Theodore; Mitchell, Stacey; Schroer, Lee; Klasen, Matthew; Ingram, Amir
Cc: Loop, Travis; Lalley, Cara; Kavlock, Robert; Hauchman, Fred; Schoeny, Rita; Reed, Khesha; Firestone, Michael; Penman, Crystal; Gentry, Nathan; Foos, Brenda; Conerly, Octavia
Subject: Materials for FDA-EPA Fish Advice briefing

It looks as if the briefing materials are not yet attached to the invitation for tomorrow's meeting, so here they are.

-----Original Appointment-----
From: Meiburg, Stan
Sent: Thursday, September 10, 2015 10:21 AM
To: Meiburg, Stan; Larimer, Lisa; Wathen, John; Hisel-Mccoy, Sara; Southerland, Elizabeth; Kopocis, Ken; Gilinsky, Ellen; Burke, Thomas; Etzel, Ruth; Coopwood, Theodore; Mitchell, Stacey; Schroer, Lee; Klasen, Matthew; Ingram, Amir

Cc: Loop, Travis; Lalley, Cara; Kavlock, Robert; Hauchman, Fred; Schoeny, Rita; Reed, Khesha; Firestone, Michael; Penman, Crystal; Gentry, Nathan; Foos, Brenda; Conerly, Octavia
Subject: FDA-EPA Fish Advice
When: Tuesday, September 22, 2015 11:00 AM-11:45 AM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomARN3530CFTB/DC-Ariel-Rios-AO

Point of Contact for the Meeting: Lisa Larimer 566-1017
SCt: Denise Anderson, 564-1782

Call In # 8662993188 / Ex. 6 - Personal Privacy

Purpose:	Share the final joint FDA-EPA fish advice with EPA senior leadership. HHS senior leadership is receiving a comparable briefing. The workgroup's goal is to announce the advice in September/October 2015, contingent upon timing of review by HHS and OMB.
Background:	An FDA-EPA workgroup has developed an update to the March 2004 fish advisory on mercury in fish and shellfish. The advice recommends consumption frequencies for the target audience of pregnant and breastfeeding women, women who could become pregnant, and children.
Last possible date for the meeting:	After 9/9/15 and before 9/25/15
EPA Staff (Required):	OW: Lisa Larimer, John Wathen, Sara Hisel-McCoy, Elizabeth Southerland, Ken Kopocis, Ellen Gilinsky ORD: Thomas Burke OA: Ruth Etzel, Theodore Coopwood OGC: Stacey Mitchell, Lee Schroer
EPA Staff (Optional):	OW: Travis Loop, Cara Lalley ORD: Robert Kavlock, Fred Hauchman, Rita Schoeny OA: Khesha Reed, Michael Firestone

<< File: Briefing Memo FDA-EPA fish advice.docx >>

To: Larimer, Lisa[Larimer.Lisa@epa.gov]
Cc: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Gentry, Nathan
Sent: Thur 9/29/2016 7:20:55 PM
Subject: RE: Meeting request with Tom Burke re: FDA-EPA fish advice

Tom is unavailable the weeks of October 17 and 31, and Lynn is unavailable the week of October 24. I've scheduled this meeting at the first available time, on November 7.

Nathan Gentry

Scheduler for Tom Burke, Lek Kadeli and Bob Kavlock

EPA Office of Research and Development

Phone: 202-564-9084

Fax: 202-565-2430

From: Larimer, Lisa
Sent: Thursday, September 29, 2016 12:22 PM
To: Gentry, Nathan <Gentry.Nathan@epa.gov>
Cc: Deener, Kathleen <Deener.Kathleen@epa.gov>
Subject: Meeting request with Tom Burke re: FDA-EPA fish advice

Hi Nathan,

Kacee suggested I contact you to set up a meeting with Dr. Burke. We would like to have it, if possible, the week of Oct. 17 or 24. The invitees would be:

From ORD – Tom Burke, Kacee Deener, Lynn Flowers

From OW – Elizabeth (Betsy) Southerland, Lisa Larimer

One hour should be sufficient. To help with scheduling Betsy Southerland, I suggest you contact Jeanette Martin, 202-566-0984.

Please let me know of any additional information you may need.

Thanks,

Lisa

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Smith, Kelley[Smith.Kelley@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]
Cc: Maguire, Megan[Maguire.Megan@epa.gov]; Linkins, Samantha[Linkins.Samantha@epa.gov]
From: Hubbard, Carolyn
Sent: Tue 12/1/2015 5:51:32 PM
Subject: RE: Reminder: Briefing Materials for Dr. Burke: 11.30.2015 - 12.10.2015

Hi Kelley and Kacee- what do you need for the conversation that Tom wants to have with Dan about the Olive Oil media inquiry?

Carolyn Hubbard

ORD Communications

202-564-2189

202-379-6744

From: Smith, Kelley
Sent: Tuesday, December 01, 2015 12:01 PM
To: Gwinn, Maureen <gwinn.maureen@epa.gov>; Plotkin, Viktoriya <Plotkin.Viktoriya@epa.gov>; Maguire, Megan <Maguire.Megan@epa.gov>; Linkins, Samantha <Linkins.Samantha@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>; Robbins, Chris <Robbins.Chris@epa.gov>; Piantanida, David <Piantanida.David@epa.gov>; Hannon, Arnita <Hannon.Arnita@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Dutton, Steven <Dutton.Steven@epa.gov>; Patel, Molini <Patel.Molini@epa.gov>; Luben, Tom <Luben.Tom@epa.gov>; Fegley, Robert <Fegley.Robert@epa.gov>; Frithsen, Jeff <Frithsen.Jeff@epa.gov>; Costa, Dan <Costa.Dan@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Linkins, Samantha <Linkins.Samantha@epa.gov>; Tracy, Tom <Tracy.Tom@epa.gov>; Smith, Kelley <Smith.Kelley@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>
Cc: Corona, Elizabeth <Corona.Elizabeth@epa.gov>; Gentry, Nathan <Gentry.Nathan@epa.gov>; Osaka, Anna <Osaka.Anna@epa.gov>; Walters, Brandon <Walters.Brandon@epa.gov>
Subject: RE: Reminder: Briefing Materials for Dr. Burke: 11.30.2015 - 12.10.2015

Good Morning,

Please provide the briefing materials noted below to Kelley Smith, Nathan Gentry, and Anna

Osaka (Smith.Kelley@epa.gov; Gentry.Nathan@epa.gov; Osaka.Anna@epa.gov) by 3:00 PM two business days prior your meeting/event with Dr. Burke. If materials are not received by 3:00 PM two business days prior to the meeting/event, it may be rescheduled or canceled.

Note: Dr. Burke is out of the office this Wednesday, so if possible please submit the items for this Thursday by 3:00 PM today.

Briefing Materials Tracker

Meeting Date	Title	POC for Materials	Notes	Materials Received
12.2.2015	Media Inquiry on Olive/Fish Oil	Dan Costa, Caroyln Hubbard, and Sam Linkins	Agenda and any other supporting briefing materials. Partial Materials received on 11.30.2015	
12.3.2015	General Burke/Battaglia	Amy Battaglia	No Materials needed	11.25.2015
12.3.2015	National Associations Outreach Meeting	Arnita Hannon and Kacee Deener	Final Agenda and any other supporting briefing materials. Drafts received on 11.23.2015	
12.3.2015	Final Integrated Science Assessment (ISA) for Oxides of Nitrogen	John Vandenberg, Steve Dutton, Molini Patel, and Tom Luben	Agenda and any other supporting briefing materials. Please also detail the connection if any to the recent EPA Volkswagen enforcement actions	11.30.2015
12.2.2015	Lean Initiative Mtg with ORD	Chris Robbins via David Piantanida	Background materials on hand from 11.23.2015. Dr. Burke needs an update that clearly details the highlights the achievements from 2015 and plans for 2016 (Contact Kelley Smith if more context is needed).	
12.3.2015	Fish Advice Meeting	Kacee Deener	Agenda and any other supporting briefing materials	
12.4.2015	Fracking Strategy Discussion	Jeff Frithsen	Agenda and any other supporting briefing materials	
12.7.2015	BOSC Executive	Tom Tracy, Maureen Gwinn,	Agenda and any other	

	Committee F-to-F mtg	and Kelley Smith	supporting briefing materials
12.7.2015	Monday EC Mtg	Elizabeth Blackburn via Anna Osaka or Viktoryia Plotkin	Final Agenda, Draft PPT for Dr.'s Kavlock and Burke, and any other supporting briefing materials
12.8.2015	BOSC Executive Committee F-to-F mtg	Tom Tracy, Maureen Gwinn, and Kelley Smith	Final Agenda, Draft PPT for Dr.'s Kavlock and Burke, and any other supporting briefing materials
12.9.2015	BOSC Executive Committee F-to-F mtg	Tom Tracy, Maureen Gwinn, and Kelley Smith	Final Agenda, Draft PPT for Dr.'s Kavlock and Burke, and any other supporting briefing materials
12.10.2015	BOSC Executive Committee F-to-F mtg	Tom Tracy, Maureen Gwinn, and Kelley Smith	Final Agenda, Draft PPT for Dr.'s Kavlock and Burke, and any other supporting briefing materials
12.10.2015	Chlorpyriphos Briefing	Kacee Deener	Advance request for Agenda and any other supporting briefing materials
12.10.2015	NTP Meeting	Kelley Smith	Advance request for final Agenda, attendee list, and details on other anticipated topics that may arise like Tire Crumb (drafts attached to invite). No need for remarks or PPT per Dr. Burke (draft materials on hand 12.1.2015)
12.15.2015	STPC December 2015 Meeting	Tom Sinks	Advance request for Agenda and any other supporting briefing materials
1.21.2015	Council of Environmental Deans Event	Melissa Anley-Mills and Alan Hecht	Advance request for Agenda, draft remarks for Dr. Burke, and any other supporting briefing materials
1.28.2016	Tox 21 Principals Meeting	Kacee Deener	Advance request for Agenda and any other supporting briefing materials

To: Gwinn, Maureen[gwinn.maureen@epa.gov]; Plotkin, Viktoriya[Plotkin.Viktoriya@epa.gov]; Maguire, Megan[Maguire.Megan@epa.gov]; Linkins, Samantha[Linkins.Samantha@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]; Robbins, Chris[Robbins.Chris@epa.gov]; Piantanida, David[Piantanida.David@epa.gov]; Hannon, Arnita[Hannon.Arnita@epa.gov]; Vandenberg, John[Vandenberg.John@epa.gov]; Dutton, Steven[Dutton.Steven@epa.gov]; Patel, Molini[Patel.Molini@epa.gov]; Luben, Tom[Luben.Tom@epa.gov]; Fegley, Robert[Fegley.Robert@epa.gov]; Frithsen, Jeff[Frithsen.Jeff@epa.gov]; Costa, Dan[Costa.Dan@epa.gov]; Hubbard, Carolyn[Hubbard.Carolyn@epa.gov]; Linkins, Samantha[Linkins.Samantha@epa.gov]; Tracy, Tom[Tracy.Tom@epa.gov]; Smith, Kelley[Smith.Kelley@epa.gov]; Blackburn, Elizabeth[Blackburn.Elizabeth@epa.gov]
Cc: Corona, Elizabeth[Corona.Elizabeth@epa.gov]; Gentry, Nathan[Gentry.Nathan@epa.gov]; Osaka, Anna[Osaka.Anna@epa.gov]; Walters, Brandon[Walters.Brandon@epa.gov]
From: Smith, Kelley
Sent: Tue 12/1/2015 5:01:28 PM
Subject: RE: Reminder: Briefing Materials for Dr. Burke: 11.30.2015 - 12.10.2015

Good Morning,

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12.3.2015	National Associations Outreach Meeting	Arnita Hannon and Kacee Deener	Final Agenda and any other supporting briefing materials. Drafts received on 11.23.2015	
12.3.2015	Final Integrated Science	John Vandenberg,	Agenda and any other supporting briefing materials.	11.30.2015

	Assessment (ISA) for Oxides of Nitrogen	Steve Dutton, Molini Patel, and Tom Luben	Please also detail the connection if any to the recent EPA Volkswagen enforcement actions
12.2.2015	Lean Initiative Mtg with ORD	Chris Robbins via David Piantanida	Background materials on hand from 11.23.2015. Dr. Burke needs an update that clearly details the highlights the achievements from 2015 and plans for 2016 (Contact Kelley Smith if more context is needed).
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12.7.2015	BOSC Executive Committee F-to-F mtg	Tom Tracy, Maureen Gwinn, and Kelley Smith	Agenda and any other supporting briefing materials
12.7.2015	Monday EC Mtg	Elizabeth Blackburn via Anna Osaka or Viktoryia Plotkin	Final Agenda, Draft PPT for Dr.'s Kavlock and Burke, and any other supporting briefing materials
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			topics that may arise like Tire Crumb (drafts attached to invite). No need for remarks or PPT per Dr. Burke (draft materials on hand 12.1.2015)
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1.28.2016	Tox 21 Principals Meeting	Kacee Deener	Advance request for Agenda and any other supporting briefing materials

To: Gwinn, Maureen[gwinn.maureen@epa.gov]; Plotkin, Viktoriya[Plotkin.Viktoriya@epa.gov]; Mazur, Sarah[Mazur.Sarah@epa.gov]; Linkins, Samantha[Linkins.Samantha@epa.gov]; Maguire, Megan[Maguire.Megan@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]; Piantanida, David[Piantanida.David@epa.gov]; Hannon, Arnita[Hannon.Arnita@epa.gov]; Vandenberg, John[Vandenberg.John@epa.gov]; Dutton, Steven[Dutton.Steven@epa.gov]; Patel, Molini[Patel.Molini@epa.gov]; Luben, Tom[Luben.Tom@epa.gov]; Frithsen, Jeff[Frithsen.Jeff@epa.gov]; Blackburn, Elizabeth[Blackburn.Elizabeth@epa.gov]; Robbins, Chris[Robbins.Chris@epa.gov]
Cc: Gentry, Nathan[Gentry.Nathan@epa.gov]; Osaka, Anna[Osaka.Anna@epa.gov]; Smith, Kelley[Smith.Kelley@epa.gov]; Corona, Elizabeth[Corona.Elizabeth@epa.gov]
From: Smith, Kelley
Sent: Mon 11/30/2015 4:37:02 PM
Subject: Reminder: Briefing Materials for Dr. Burke: 11.30.2015 - 12.10.2015

Good Morning,

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Briefing Materials Tracker				
Meeting Date	**Title**	**POC for Materials**	**Notes**	**Materials Received**
12.1.2015	ORD Research Delivery and Future Directions (OSWER)	Maureen Gwinn and Viktoriya Plotkin	Agenda and any other supporting briefing materials	
12.1.2015	NSTC Committee on Science	Sarah Mazur and Kacee Deener	Agenda and any other supporting briefing materials	11.23.201
12.1.2015	Pat Riz Outlook Interview	Sam Linkins and Megan Maguire via Kacee Deener	Agenda and any other supporting briefing materials	
12.2.2015	Lean Initiative Mtg with ORD	Chris Robbins via David Piantanida	Background materials on hand from 11.23.2015. Dr. Burke needs an update that clearly details the highlights the achievements from 2015 and plans for 2016 (Contact Kelley Smith if more context is needed).	
12.3.2015	General Burke/Battaglia	Amy Battaglia	No Materials needed	11.25.201
12.3.2015	National Associations Outreach Meeting	Arnita Hannon and Kacee Deener	Advance notice for EETPs for Dr. Burke (Kacee)	

12.3.2015	Final Integrated Science Assessment (ISA) for Oxides of Nitrogen	John Vandenberg, Steve Dutton, Molini Patel, and Tom Luben	Agenda and any other supporting briefing materials. Please also detail the connection if any to the recent EPA Volkswagen enforcement actions
12.3.2015	Fish Advice Meeting	Kacee Deener	Agenda and any other supporting briefing materials
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12.8.2015	BOSC Executive Committee F-to-F mtg	Maureen Gwinn and TBD?	Agenda and any other supporting briefing materials
12.9.2015	BOSC Executive Committee F-to-F mtg	Maureen Gwinn and TBD?	Agenda and any other supporting briefing materials
12.10.2015	BOSC Executive Committee F-to-F mtg	Maureen Gwinn and TBD?	Agenda and any other supporting briefing materials

To: Linkins, Samantha[Linkins.Samantha@epa.gov]; Maguire, Megan[Maguire.Megan@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]; Frithsen, Jeff[Frithsen.Jeff@epa.gov]; Gwinn, Maureen[gwinn.maureen@epa.gov]; Hannon, Arnita[Hannon.Arnita@epa.gov]; Matthews, Lisa[Matthews.Lisa@epa.gov]; LaVay, Maggie[LaVay.Maggie@epa.gov]; Vandenberg, John[Vandenberg.John@epa.gov]; Dutton, Steven[Dutton.Steven@epa.gov]; Patel, Molini[Patel.Molini@epa.gov]; Luben, Tom[Luben.Tom@epa.gov]
Cc: Blackburn, Elizabeth[Blackburn.Elizabeth@epa.gov]; Smith, Kelley[Smith.Kelley@epa.gov]; Gentry, Nathan[Gentry.Nathan@epa.gov]; Walters, Brandon[Walters.Brandon@epa.gov]; Corona, Elizabeth[Corona.Elizabeth@epa.gov]; Piantanida, David[Piantanida.David@epa.gov]
From: Osaka, Anna
Sent: Fri 11/27/2015 4:10:11 PM
Subject: Reminder: Briefing Materials for Dr. Burke: 11.30.2015 - 12.4.2015

Good Morning,

Please provide the briefing materials noted below to Kelley Smith, Nathan Gentry, and Anna Osaka (Smith.Kelley@epa.gov; Gentry.Nathan@epa.gov; Osaka.Anna@epa.gov) by 3:00 PM two business days prior your meeting/event with Dr. Burke. If materials are not received by 3:00 PM two business days prior to the meeting/event, it may be rescheduled or canceled.

Briefing Materials Tracker

Meeting Date	Title	POC for Materials	Notes	Materials Received
11.27.2015	Pat Riz Interview Prep Materials	Sam Linkins and Megan Maguire via Kacee Deener	Partial materials received on 11.24.2015.	
11.30.2015	GKM After Action Review	Eileen Naples	mtg memo, IG draft report, DOI final report, and list of questions for consideration is on hand	11.24.2015
11.30.2015	Bi-Weekly HF Status Meeting	Jeff Frithsen and Kelley Smith	Jeff and Kelley will cover meeting for Dr. Burke. Provide agenda and any other supporting briefing materials for Tom's briefing book	
11.30.2015	Call with Mathy Stanislaus	Maureen Gwinn	Agenda and any other supporting briefing materials	
11.30.2015	Monday EC Mtg	Liz Blackburn via Anna Osaka or Viktoriya Plotkin	Agenda and any other supporting briefing materials	11.25.2015
11.30.2015	Chesapeake Bay	Jeff Corbin	Materials attached to meeting	10.18.2015

	Independent Evaluator		invite	
12.1.2015	ORD Research Delivery and Future Directions (OSWER)	Maureen Gwinn and Viktoriya Plotkin	Agenda and any other supporting briefing materials	11.25.2015
12.1.2015	NSTC Committee on Science	Sarah Mazur and Kacee Deener	Agenda and any other supporting briefing materials	11.23.2015
12.1.2015	Pat Riz Outlook Interview	Sam Linkins and Megan Maguire via Kacee Deener	Partial materials received on 11.24.2015	
12.3.2015	National Associations Outreach Meeting	Arnita Hannon and Kacee Deener	Advance notice for Event Memo (Arnita) and TPs for Dr. Burke (Kacee)	
12.3.2015	R7 Kansas City Pre-Brief	Lisa Matthews, Maggie LaVay, and Kelley Smith	Advance notice for Agenda (Kelley), TPs for Tools Café (Lisa), PPT for State Directors meeting (Lisa and Maggie), and other background materials (Maggie and Lisa)	
12.3.2015	Final Integrated Science Assessment (ISA) for Oxides of Nitrogen	John Vandenberg, Steve Dutton, Molini Patel, and Tom Luben	Advance notice for Agenda and any other supporting briefing materials. Note please include info on how this ISA may relate to the EPA Volkswagen enforcement actions.	
12.3.2015	Fish Advice Meeting	Kacee Deener	Advance notice for Agenda and any other supporting briefing materials	
12.4.2015	Fracking Strategy Discussion	Jeff Frithsen	Advance notice for Agenda and any other supporting briefing materials	

Anna Osaka

U.S. EPA Office of Research and Development

Immediate Office of the Assistant Administrator

osaka.anna@epa.gov

W: 202.564.8074

C: 202.329.1552

To: Frithsen, Jeff[Frithsen.Jeff@epa.gov]; Linkins, Samantha[Linkins.Samantha@epa.gov]; Maguire, Megan[Maguire.Megan@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]; Naples, Eileen[Naples.Eileen@epa.gov]; Smith, Kelley[Smith.Kelley@epa.gov]; Gwinn, Maureen[gwinn.maureen@epa.gov]; Blackburn, Elizabeth[Blackburn.Elizabeth@epa.gov]; Osaka, Anna[Osaka.Anna@epa.gov]; Plotkin, Viktoriya[Plotkin.Viktoriya@epa.gov]; Mazur, Sarah[Mazur.Sarah@epa.gov]; Hannon, Arnita[Hannon.Arnita@epa.gov]; Matthews, Lisa[Matthews.Lisa@epa.gov]; LaVay, Maggie[LaVay.Maggie@epa.gov]; Vandenberg, John[Vandenberg.John@epa.gov]; Dutton, Steven[Dutton.Steven@epa.gov]; Patel, Molini[Patel.Molini@epa.gov]; Luben, Tom[Luben.Tom@epa.gov]
Cc: Gentry, Nathan[Gentry.Nathan@epa.gov]; Corona, Elizabeth[Corona.Elizabeth@epa.gov]; Piantanida, David[Piantanida.David@epa.gov]; Walters, Brandon[Walters.Brandon@epa.gov]
From: Smith, Kelley
Sent: Wed 11/25/2015 5:28:44 PM
Subject: Reminder: Briefing Materials for Dr. Burke: 11.26.2015 - 12.4.2015

Good Morning,

Please provide the briefing materials noted below to Kelley Smith, Nathan Gentry, and Anna Osaka (Smith.Kelley@epa.gov; Gentry.Nathan@epa.gov; Osaka.Anna@epa.gov) by 3:00 PM two business days prior your meeting/event with Dr. Burke. If materials are not received by 3:00 PM two business days prior to the meeting/event, it may be rescheduled or canceled.

Note: Because of the Thanksgiving holiday please submit items for Monday November 30 by 3:00 PM today if possible.

Briefing Materials Tracker

Meeting Date	Title	POC for Materials	Notes	Materials Received
11.24.2015	Bi-weekly HF Check In	Jeff Frithsen	This meeting has been canceled. Please still submit memo detailing current status of HF efforts	
11.26.2015	Thanksgiving (Holiday)	N/A	No Materials needed	
11.27.2015	Pat Riz Interview Prep Materials	Sam Linkins and Megan Maguire via Kacee Deener	Partial materials received on 11.24.2015.	
11.30.2015	GKM After Action Review	Eileen Naples	mtg memo, IG draft report, DOI final report, and list of questions for consideration is on hand	11.24.2015

11.30.2015	Bi-Weekly HF Status Meeting	Jeff Frithsen and Kelley Smith	Jeff and Kelley will cover meeting for Dr. Burke. Provide agenda and any other supporting briefing materials for Tom's briefing book	
11.30.2015	Call with Mathy Stanislaus	Maureen Gwinn	Agenda and any other supporting briefing materials	
11.30.2015	Monday EC Mtg	Liz Blackburn via Anna Osaka or Viktoriya Plotkin	Agenda and any other supporting briefing materials	
11.30.2015	Chesapeake Bay Independent Evaluator	Jeff Corbin	Materials attached to meeting invite	10.18.2015
12.1.2015	ORD Research Delivery and Future Directions (OSWER)	Maureen Gwinn and Viktoriya Plotkin	Agenda and any other supporting briefing materials	
12.1.2015	NSTC Committee on Science	Sarah Mazur and Kacee Deener	Agenda and any other supporting briefing materials	11.23.2015
12.1.2015	Pat Riz Outlook Interview	Sam Linkins and Megan Maguire via Kacee Deener	Partial materials received on 11.24.2015	
12.2.2015	No Materials Needed	N/A	No Materials needed	
12.3.2015	General Burke/Battaglia	Amy Battaglia	No Materials needed	11.25.2015
12.3.2015	National Associations Outreach Meeting	Arnita Hannon and Kacee Deener	Advance notice for Event Memo (Arnita) and TPs for Dr. Burke (Kacee)	
12.3.2015	R7 Kansas City Pre-Brief	Lisa Matthews, Maggie LaVay, and Kelley Smith	Advance notice for Agenda (Kelley), TPs for Tools Café (Lisa), PPT for State Directors meeting (Lisa and Maggie), and other background materials (Maggie and Lisa)	
12.3.2015	Final Integrated Science Assessment (ISA) for Oxides of Nitrogen	John Vandenberg, Steve Dutton, Molini Patel, and Tom Luben	Advance notice for Agenda and any other supporting briefing materials. Note please include info on how this ISA may relate to the EPA Volkswagen enforcement	

			actions.
12.3.2015	Fish Advice Meeting	Kacee Deener	Advance notice for Agenda and any other supporting briefing materials
12.4.2015	Fracking Strategy Discussion	Jeff Frithsen	Advance notice for Agenda and any other supporting briefing materials

To: Smith, Kelley[Smith.Kelley@epa.gov]
Cc: Deener, Kathleen[Deener.Kathleen@epa.gov]; Osaka, Anna[Osaka.Anna@epa.gov]; Gentry, Nathan[Gentry.Nathan@epa.gov]
From: Mazur, Sarah
Sent: Tue 11/24/2015 6:40:19 PM
Subject: Re: Reminder: Briefing Materials for Dr. Burke: 11.20-27.2015

The main thing is that he should be prepared to talk to the priorities Kacee submitted for topics for COS emphasis over the next year. I haven't yet opened what Kacee sent, but other agencies (see excel file) raised big data, citizen science and science credibility as topics, so I imagine there will be lively discussion around these and what the "it" is that cos could be doing.

Sent from my iPhone

On Nov 24, 2015, at 1:11 PM, Smith, Kelley <Smith.Kelley@epa.gov> wrote:

> Saw those and saved them to Tom's google drive. Thank you for sending them over and for flagging the additional document.
>
> Do you think Tom and Bob will need any talking points for this meeting?
>
> Best,
>
> KS
>
> Kelley Smith
>
> Program Advisor
>
> Office of Research and Development
>
> Environmental Protection Agency
>
> 202.564.2308 (Desk)
>
> 202.308.6587 (Cell)

Smith.Kelley@epa.gov

From: Mazur, Sarah
Sent: Tuesday, November 24, 2015 12:27 PM
To: Smith, Kelley <Smith.Kelley@epa.gov>
Cc: Deener, Kathleen <Deener.Kathleen@epa.gov>; Osaka, Anna <Osaka.Anna@epa.gov>; Gentry, Nathan <Gentry.Nathan@epa.gov>
Subject: Re: Reminder: Briefing Materials for Dr. Burke: 11.20-27.2015

Hi Kelley,

Materials for the nstc meeting were sent around yesterday. You should have all received them. There will be one more document from Afua Bruce at OSTP and perhaps an update early next week.

Happy Thanksgiving!

Sarah

Sent from my iPhone

On Nov 24, 2015, at 10:13 AM, Smith, Kelley <Smith.Kelley@epa.gov> wrote:

> Good Morning,
>
> Please provide the briefing materials noted below to Kelley Smith, Nathan Gentry, and Anna Osaka (Smith.Kelley@epa.gov; Gentry.Nathan@epa.gov; Osaka.Anna@epa.gov) by 3:00 PM two business days prior your meeting/event with Dr. Burke. If materials are not received by 3:00 PM two business days prior to the meeting/event, it may be rescheduled or canceled.
>
> **Note:** Because of the Thanksgiving holiday please submit items for Monday November 30 by 3:00 PM today if possible.

Briefing Materials Tracker

Meeting Date	Title	POC for Materials	Notes	Materials Received
11.24.2015	Bi-weekly HF Check In	Jeff Frithsen	This meeting has been canceled. Please still submit memo detailing current status of HF efforts	
11.24.2015	R7 State Directors Mtg	Lisa Matthews and Maggie LaVay	(Advance request) Need first draft of powerpoint for State Directors mtg on 12.7.2015 and first draft of TPs for Tools Café on 12.8.2015	
11.25.2015	Tire Crumb Teleconference	Fred Hauchman	Agenda and any other supporting briefing materials	
11.25.2015	General Burke/Sonich-Mullin (by phone)	Cindy Sonich-Mullin	Agenda and any other supporting briefing materials	
11.25.2015	General Discussion	Janet McCabe (Kacee Deener)	Meeting topic summary on hand	11.19.2015
11.25.2015	General with Kacee	Kacee Deener	Agenda and any other supporting briefing materials	11.24.2015
11.25.2015	Scheduling Discussion	Kelley Smith	Scheduling Materials	11.24.2015
11.26.2015	Thanksgiving (Holiday)	N/A	No Materials needed	
11.27.2015	TBD		No Materials needed at this time	
11.30.2015	GKM After Action Review	Eileen Naples	Agenda and any other supporting briefing materials	
11.30.2015	Bi-Weekly HF Status Meeting	Jeff Frithsen and Kelley Smith	Jeff and Kelley will cover meeting for Dr. Burke. Provide agenda and any other supporting briefing materials for Tom's briefing book	
11.30.2015	Call with Mathy Stanislaus	Maureen Gwinn	Agenda and any other supporting briefing materials	
11.30.2015	Monday EC Mtg	Liz Blackburn via Anna Osaka or Viktoriya Plotkin	Agenda and any other supporting briefing materials	
11.30.2015	Chesapeake Bay Independent	Jeff Corbin	Materials attached to meeting	10.18.2015

	Evaluator	invite		
12.1.2015	Howard University Partnership Mtg	William F. Cooper and Jim Johnson	Agenda and any other supporting briefing materials	
12.1.2015	ORD Research Delivery and Future Directions (OSWER)	Maureen Gwinn and Viktoriya Plotkin	Agenda and any other supporting briefing materials	
12.1.2015	NSTC Committee on Science	Sarah Mazur and Kacee Deener	Agenda and any other supporting briefing materials	11.23.2015
12.1.2015	SSWR Direction	Suzanne VanDrunick	Agenda and any other supporting briefing materials	
12.1.2015	Monthly IRIS Update	Maureen Gwinn	Agenda and any other supporting briefing materials	
12.2.2015	TBD	N/A	No Materials needed	
12.3.2015	National Associations Outreach Meeting	Arnita Hannon and Kacee Deener	Advance notice for Event Memo (Arnita) and TPs for Dr. Burke (Kacee)	
12.3.2015	R7 Kansas City Pre-Brief	Lisa Matthews, Maggie LaVay, and Kelley Smith	Advance notice for Agenda (Kelley), TPs for Tools Café (Lisa), PPT for State Directors meeting (Lisa and Maggie), and other background materials (Maggie and Lisa)	
12.3.2015	Final Integrated Science Assessment (ISA) for Oxides of Nitrogen	John Vandenberg, Steve Dutton, Molini Patel, and Tom Luben	Advance notice for Agenda and any other supporting briefing materials	
12.3.2015	Fish Advice Meeting	Kacee Deener	Advance notice for Agenda and any other supporting briefing materials	

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Smith, Kelley
Sent: Wed 11/18/2015 10:41:49 PM
Subject: RE: Briefing Book for Tomorrow

Yes- I anticipated that he would need some time to prep for [Ex. 5 - Deliberative Process] mtg and the fish meeting with the administrator.

1030-1 is open and is held as office work time / lunch

We can ask tom if he is ok with us using some of that time in our 9am.

Best,

KS

Kelley Smith

Program Advisor

Office of Research and Development

Environmental Protection Agency

202.564.2308 (Desk)

202.308.6587 (Cell)

Smith.Kelley@epa.gov

From: Deener, Kathleen
Sent: Wednesday, November 18, 2015 5:03 PM
To: Smith, Kelley <Smith.Kelley@epa.gov>
Subject: Re: Briefing Book for Tomorrow

Kelley - just FYI, I'm going over to the tire crumb meeting with Tom.

Also - is there any small window of time when Tom, Fred and I could huddle before the WH meeting? I can't really see his calendar from my iPhone.

Thanks!

Kacee

Sent from my iPhone

On Nov 18, 2015, at 4:58 PM, Smith, Kelley <Smith.Kelley@epa.gov> wrote:

> Good Afternoon Tom,
>
> I hope your flight back to Baltimore went well! I wanted to reach out to flag that your briefing materials for tomorrow are in the google drive and your binder will be at your desk when you arrive tomorrow morning. In addition there are two meetings of note tomorrow that I have listed below.
>
> Do you need Kacee or I to put together any last min items for either meeting?
>
> 1:30 – 2:00 PM **Fish Advice Meeting**
>
> *Attendees:* Administrator, Joel Beauvais, and you
>
> *Note:* This meeting was at a different date but was moved up per Nathan.

3:00 – 4:00 PM

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Note: Briefing materials are in the google drive and are in your binder.

Best,

KS

Kelley Smith

Program Advisor

Office of Research and Development

Environmental Protection Agency

202.564.2308 (Desk)

202.308.6587 (Cell)

Smith.Kelley@epa.gov

To: Flowers, Lynn[Flowers.Lynn@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]
Cc: Phillips, Linda[Phillips.Linda@epa.gov]; Ross, Mary[Ross.Mary@epa.gov]
From: Bussard, David
Sent: Tue 10/20/2015 4:37:30 PM
Subject: RE: information on Hg and fish for today's discussion
Example Calculations 10-20-15-rev_pagelayout.xlsx

If any want to print out the spreadsheet, I could not figure out an easy way to make one tab easy to print, but for the second one I got it to fit well on three pages with repeated titles in attached.

From: Flowers, Lynn
Sent: Tuesday, October 20, 2015 12:12 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; Phillips, Linda <Phillips.Linda@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>
Subject: information on Hg and fish for today's discussion

Kacee:

There are two attachments for today's check in meeting with you:

1) A spreadsheet of calculations as requested (note that there are two tabs), and

2) A write up of the analysis and results.

I also have a short list of issues to note:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lynn Flowers, PhD, DABT

Associate Director for Health

National Center for Environmental Assessment

US EPA

Washington, DC

703-347-8537

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Burke, Thomas
Sent: Tue 10/20/2015 12:28:18 AM
Subject: Fwd: FISH_CHART_H_9.2.pdf

FYI

Thomas A. Burke, PhD, MPH
Deputy Assistant Administrator
EPA Science Advisor
Office of Research and Development
202-564-6620
burke.thomas@epa.gov

Begin forwarded message:

From: "Birnbaum, Linda (NIH/NIEHS) [E]" <birnbaumls@niehs.nih.gov>
Date: October 19, 2015 at 7:56:55 PM EDT
To: "Burke, Thomas" <Burke.Thomas@epa.gov>
Subject: Re: FISH_CHART_H_9.2.pdf

Ex. 5 - Deliberative Process

Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S

Director, National Institute of Environmental Health Sciences

and National Toxicology Program

phone: 919-541-3201

fax: 919-541-2260

e-mail: birnbaumls@niehs.nih.gov

On Oct 16, 2015, at 10:25 AM, Burke, Thomas <Burke.Thomas@epa.gov> wrote:

Thomas A. Burke, PhD, MPH
Deputy Assistant Administrator
EPA Science Advisor
Office of Research and Development
202-564-6620

burke.thomas@epa.gov

Begin forwarded message:

From: "Burke, Thomas" <Burke.Thomas@epa.gov>
Date: October 16, 2015 at 7:52:53 AM EDT
To: "Burke, Thomas" <Burke.Thomas@epa.gov>, Tom Burke
Ex. 6 - Personal Privacy
Subject: FISH_CHART_H_9.2.pdf

Ex. 5 - Deliberative Process

<FISH_CHART_H_9.2.pdf>

Thomas A. Burke, PhD, MPH
Deputy Assistant Administrator
EPA Science Advisor
Office of Research and Development
202-564-6620
burke.thomas@epa.gov

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
Cc: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Hisel-Mccoy, Sara
Sent: Thur 10/8/2015 4:04:56 PM
Subject: FW: Update on FDA-EPA fish advice - input requested

Kacee - It is Ken's expectation that this is a next steps meeting for Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Hisel-Mccoy, Sara
Sent: Thursday, October 08, 2015 12:02 PM
To: Larimer, Lisa; Deener, Kathleen
Cc: Southerland, Elizabeth; Wathen, John
Subject: RE: Update on FDA-EPA fish advice - input requested

Kacee – Just a quick update to our short discussion. You asked about the conversation regarding

Ex. 5 - Deliberative Process

Thanks again,

Sara

From: Larimer, Lisa
Sent: Thursday, October 08, 2015 11:02 AM
To: Deener, Kathleen
Cc: Southerland, Elizabeth; Hisel-Mccoy, Sara; Wathen, John
Subject: Update on FDA-EPA fish advice - input requested

Kacee-

We have made improvements to the fish advice materials a Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

The changes are :

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Deener, Kathleen[Deener.Kathleen@epa.gov]; Gentry, Nathan[Gentry.Nathan@epa.gov]; Conerly, Octavia[Conerly.Octavia@epa.gov]
Cc: Penman, Crystal[Penman.Crystal@epa.gov]
From: Bethel, Heidi
Sent: Mon 1/4/2016 2:34:34 PM
Subject: RE: FDA/EPA Meeting With Subject Matter Experts to Discuss Fish Advice Call in 1-**Ex. 6 - Personal Privacy**** TO BE RESCHEDULED**

Hi All,
From my discussion with Joel Beauvais this morning, he thinks this meeting is a carry-over meeting from last year and is most likely no longer needed **Ex. 5 - Deliberative Process** **Ex. 5 - Deliberative Process** please let me know. Otherwise, Crystal and I will remove this meeting from the calendar for tomorrow.
Thanks,
Heidi
(202) 566-2054

From: Deener, Kathleen
Sent: Monday, January 04, 2016 9:00 AM
To: Gentry, Nathan <Gentry.Nathan@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>
Cc: Penman, Crystal <Penman.Crystal@epa.gov>; Bethel, Heidi <Bethel.Heidi@epa.gov>
Subject: RE: FDA/EPA Meeting With Subject Matter Experts to Discuss Fish Advice Call in 1-866-299-3188 passcode 2029992299 *** TO BE RESCHEDULED**

That's my understanding, too. Octavia - I can coordinate the ORD subject matter experts who will participate in this meeting (I will participate, along with 2 or 3 others). Let me know what dates you're considering.

Kacee Deener, MPH
Senior Science Advisor
Office of Research and Development
(ph) 202.564.1990 | (mobile) 202.510.1490
deener.kathleen@epa.gov

From: Gentry, Nathan
Sent: Monday, January 04, 2016 8:57 AM
To: Conerly, Octavia <Conerly.Octavia@epa.gov>
Cc: Penman, Crystal <Penman.Crystal@epa.gov>; Bethel, Heidi <Bethel.Heidi@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>
Subject: RE: FDA/EPA Meeting With Subject Matter Experts to Discuss Fish Advice Call in 1-866-299-3188 passcode 2029992299 *** TO BE RESCHEDULED**

My understanding was that Tom would not be participating in this meeting, and asked OW/Crystal to take the lead in scheduling.

Nathan Gentry
Scheduler for Tom Burke, Lek Kadeli and Bob Kavlock
EPA Office of Research and Development
Phone: 202-564-9084
Fax: 202-565-2430

From: Conerly, Octavia
Sent: Monday, January 04, 2016 7:53 AM
To: Gentry, Nathan <Gentry.Nathan@epa.gov>
Cc: Penman, Crystal <Penman.Crystal@epa.gov>; Bethel, Heidi <Bethel.Heidi@epa.gov>
Subject: FW: FDA/EPA Meeting With Subject Matter Experts to Discuss Fish Advice Call in 1-866-299-3188 passcode 2029992299 *** TO BE RESCHEDULED**

Hi Nathan,
Has anyone else contacted you regarding Tom's availability for this meeting? We need to get it rescheduled as soon as we can. Thanks in advance.

Octavia Conerly
Special Assistant to the Office Director
Office of Science and Technology
1200 Pennsylvania Ave. NW MC 4304T
Room 5231H
Washington, DC 20460
EMAIL: conerly.octavia@epa.gov
PHONE: (202) 566-1094
FAX: (202) 566-0441

From: Conerly, Octavia
Sent: Tuesday, December 22, 2015 5:33 PM
To: Gentry, Nathan <Gentry.Nathan@epa.gov>
Cc: Penman, Crystal <Penman.Crystal@epa.gov>; Bethel, Heidi <Bethel.Heidi@epa.gov>
Subject: FDA/EPA Meeting With Subject Matter Experts to Discuss Fish Advice Call in 1-866-299-3188 passcode 2029992299 *** TO BE RESCHEDULED**

Hi Nathan,
We would like Tom Burke to attend this meeting with FDA. Can you provide some dates/times that Tom is available to meet? Thanks in advance. Happy New Year!

Subject: FDA/EPA Meeting With Subject Matter Experts to Discuss Fish Advice Call in Ex. 6 - Personal Privacy *** TO BE RESCHEDULED**
Location: EPA 1201 Constitution Ave NW, Washington DC 20460 WJCE 3233 Please call 202-564-5700 for escort

Start:	Tue 1/5/2016 4:00 PM
End:	Tue 1/5/2016 5:30 PM
Show Time As:	Tentative
Recurrence:	(none)
Meeting Status:	Meeting organizer
Organizer:	Beauvais, Joel
Required Attendees:	Beauvais, Joel; Jeremy.Sharp@fda.hhs.gov; Susan.Mayne@fda.hhs.gov; Susan.Bernard@fda.hhs.gov; Deborah.Smegal@fda.hhs.gov; Sharon.Natanblut@fda.hhs.gov; Sherri.Dennis@fda.hhs.gov; William.Jones@fda.hhs.gov
Optional Attendees:	Saben, Alyson L; Gilinsky, Ellen
Categories:	Blue Category

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Barash, Shari
Sent: Thur 10/1/2015 3:22:16 PM
Subject: Fwd: Please print copies of Fish Advice power point for the 11 am meeting with ORD
FDA-EPA Fish Advice for ORD_final.pptx
ATT00001.htm

In case you can get this in transit

Sent from my iPhone

Begin forwarded message:

From: "Barash, Shari" <Barash.Shari@epa.gov>
Date: October 1, 2015 at 10:25:23 AM EDT
To: Evelyn McRae <McRae.Evelyn@epa.gov>, Sara Hisel-McCoy <Hisel-McCoy.Sara@epa.gov>
Cc: Lisa Larimer <Larimer.Lisa@epa.gov>
Subject: Please print copies of Fish Advice power point for the 11 am meeting with ORD

Print at least one color copy – one slide per page version for Tom Burke

Shari Z. Barash

Acting Chief

National Branch

Office of Water

US EPA

Washington, DC

202-566-0996

barash.shari@epa.gov

To: Smith, Kelley[Smith.Kelley@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]
Cc: Blackburn, Elizabeth[Blackburn.Elizabeth@epa.gov]
From: gentry.nathan Ex. 6 - Personal Privacy
Sent: Wed 12/23/2015 12:33:37 AM
Subject: Fw: FDA/EPA Meeting With Subject Matter Experts to Discuss Fish Advice Call in Ex. 6 - Personal Privacy Ex. 6 - Personal Privacy *** TO BE RESCHEDULED**

You can check with Tom, but I'm fairly certain this is the meeting he said should be attended at the staff level by Kacee, but he would not participate.

From: Conerly, Octavia
Sent: Tuesday, December 22, 2015 5:33 PM
To: Nathan Gentry
Cc: Penman, Crystal, Bethel, Heidi

Hi Nathan,
We would like Tom Burke to attend this meeting with FDA. Can you provide some dates/times that Tom is available to meet? Thanks in advance. Happy New Year!

Subject: FDA/EPA Meeting With Subject Matter Experts to Discuss Fish Advice Call in Ex. 6 - Personal Privacy Ex. 6 - Personal Privacy *** TO BE RESCHEDULED**
Location: EPA 1201 Constitution Ave NW, Washington DC 20460 WJCE 3233 Please call Ex. 6 - Personal Privacy Ex. 6 - Personal Privacy for escort

Start: Tue 1/5/2016 4:00 PM
End: Tue 1/5/2016 5:30 PM
Show Time As: Tentative

Recurrence: (none)

Meeting Status: Meeting organizer

Organizer: Beauvais, Joel
Required Attendees: Beauvais, Joel; Jeremy.Sharp@fda.hhs.gov; Susan.Mayne@fda.hhs.gov; Susan.Bernard@fda.hhs.gov; Deborah.Smegal@fda.hhs.gov; Sharon.Natanblut@fda.hhs.gov; Sherri.Dennis@fda.hhs.gov; William.Jones@fda.hhs.gov
Optional Attendees: Saben, Alyson L; Gilinsky, Ellen

Categories: Blue Category

To: Schoeny, Rita[Schoeny.Rita@epa.gov]
Cc: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Fegley, Robert
Sent: Tue 9/29/2015 2:11:44 PM
Subject: Re: Follow-up Information on EPA-FDA Fish Advice

Rita let's talk. I think Kacee is asking a different question

On Sep 29, 2015, at 9:35 AM, Schoeny, Rita <Schoeny.Rita@epa.gov> wrote:

Ex. 5 - Deliberative Process

From: Deener, Kathleen
Sent: Monday, September 28, 2015 6:18 PM
To: Fegley, Robert
Cc: Schoeny, Rita
Subject: RE: Follow-up Information on EPA-FDA Fish Advice

Thanks Bob! I just left a voicemail message to give you some more context about my
Ex. 5 - Deliberative Process

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Fegley, Robert

Sent: Monday, September 28, 2015 6:10 PM
To: Deener, Kathleen
Cc: Schoeny, Rita
Subject: FW: Follow-up Information on EPA-FDA Fish Advice

Kacee, I have a call into Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Hisel-Mccoy, Sara
Sent: Monday, September 28, 2015 5:27 PM
To: Fegley, Robert
Cc: Deener, Kathleen; Hauchman, Fred
Subject: Re: Follow-up Information on EPA-FDA Fish Advice

Great. ThAnks for the heads up. Kacee also had a question about Ex. 5 - Deliberative Process that we are working on. Do you know, are there any other outstanding questions you have? Thanks, Sara

Sara Hisel-McCoy

Standards and Health Protection Division

202 566-1649

On Sep 28, 2015, at 5:24 PM, Fegley, Robert <Fegley.Robert@epa.gov> wrote:

Sara, Kacee did share this with me earlier this afternoon.

From: Hauchman, Fred
Sent: Monday, September 28, 2015 5:23 PM
To: Hisel-Mccoy, Sara

Cc: Deener, Kathleen; Southerland, Elizabeth; Barash, Shari; Larimer, Lisa; Fegley, Robert
Subject: Re: Follow-up Information on EPA-FDA Fish Advice

Sara,

FYI, I'm out of the office this week. Bob Fegley is coordinating our input with Kacee.

Fred

Sent from my iPhone

On Sep 28, 2015, at 5:53 PM, Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov> wrote:

> KaCee and Fred –
>
> Hello. We're following up with more information related to the FDA-EPA fish advice. Also, as Betsy mentioned in a previous note, FDA is meeting with the HHS Secretary on Wednesday so we would very much like to get feedback as soon as possible.
>
> Sara
>
> Focus on mercury
>
> In the meeting last week, we heard the concern that the advice is limited to only mercury. However, focusing on mercury in our joint advice is on target because mercury collects in the muscle tissue (fillet) and nothing in the preparation/cooking process can be done to reduce risks from mercury. Consumers can reduce risks from PCBs and other organic contaminants through the cleaning and cooking process because those contaminants collect in the fatty tissues, a large portion of which can be removed when the fish are prepped for cooking. The Q&A for the FDA-EPA fish advice discusses removing skin, belly fat, and internal organs before cooking. In addition, most of the state advisories for locally caught fish are for mercury (81% in 2011). Fifty states monitor for mercury and 39 monitor for PCBs.

Ex. 5 - Deliberative Process

The water program uses mean mercury concentrations. The FDA-EPA fish advice is based upon mean mercury concentrations in commercial fish and how often those fish can be eaten without exceeding the RfD. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

As a sensitivity analysis, we Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Other considerations

Ex. 5 - Deliberative Process

FINFISH/SHELLFISH	Mean Hg conc (ppm)
ANCHOVIES	0.02
BLUEFISH	0.37
BUFFALO FISH	0.14
CARP	0.11
CATFISH	0.02
CLAM	0.01
COD	0.11
CRAB	0.06
CRAWFISH	0.03
CROAKER, ATLANTIC	0.07
CROAKER, WHITE	0.29
FLATFISH: FLOUNDER	0.05
FLATFISH: PLAICE	0.04
FLATFISH: SOLE	0.08
GROUPER	0.45
HADDOCK	0.06
HAKE	0.08
HALIBUT	0.24
HERRING	0.08
LOBSTER, AMERICAN	0.11
LOBSTER, SPINY	0.09
MAHI MAHI	0.18
MARLIN	0.49
MONKFISH	0.16

Ex. 5 - Deliberative Process

MULLET	0.05
ORANGE ROUGHY	0.57
OYSTER	0.01
PERCH, FRESHWATER	0.15
PERCH, OCEAN	0.12
PICKEREL	0.09
POLLOCK	0.03
ROCKFISH	0.23
SABLE FISH	0.36
SALMON	0.02
SALMON, CANNED	0.01
SARDINE	0.01
SCALLOP	0.00
SCORPIONFISH	0.23
SEA BASS, BLACK	0.13
SEA BASS, CHILEAN	0.35
SEA BASS, STRIPED	0.07
SHAD	0.04
SHARK	0.98
SHEEPSHEAD	0.09
SHRIMP	0.01
SMELT	0.08
SNAPPER	0.17
SQUID	0.02
SWORDFISH	1.00
TILAPIA	0.01
TILEFISH, ATLANTIC	0.14
TROUT, FRESHWATER	0.07
TUNA, CANNED (ALBACORE)	0.35
TUNA, CANNED (LIGHT)	0.13
TUNA, FR/FZN ALBACORE	0.36

Ex. 5 - Deliberative Process

TUNA, FR/FZN BIGEYE	0.69
TUNA, FR/FZN SKIPJACK	0.14
TUNA, FR/FZN YELLOWFIN	0.35
WEAKFISH (SEA TROUT)	0.23
WHITEFISH	0.09
WHITING	0.05

Ex. 5 - Deliberative Process

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
Cc: Corr, Elizabeth[Corr.Elizabeth@epa.gov]; Conerly, Octavia[Conerly.Octavia@epa.gov]; Campbell, Ann[Campbell.Ann@epa.gov]; Gentry, Nathan[Gentry.Nathan@epa.gov]
From: Gude, Karen
Sent: Tue 10/18/2016 2:29:02 PM
Subject: RE: 10/26 Meeting on EPA-FDA Fish Advice

Thanks, Kacee!

Nathan, If you have questions or need additional info, please let me know.

From: Deener, Kathleen
Sent: Tuesday, October 18, 2016 10:28 AM
To: Gude, Karen <Gude.Karen@epa.gov>
Cc: Corr, Elizabeth <Corr.Elizabeth@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>; Gentry, Nathan <Gentry.Nathan@epa.gov>
Subject: RE: 10/26 Meeting on EPA-FDA Fish Advice

Hi Karen,

I think we can probably do this, but please check in with Nathan Gentry, Tom's scheduler, to see if this is possible given his schedule that day. I've added Nathan here so he can chime in.

Kacee Deener, MPH
Senior Science Advisor
Office of Research and Development
(ph) 202.564.1990 | (mobile) 202.510.1490
deener.kathleen@epa.gov

From: Gude, Karen
Sent: Tuesday, October 18, 2016 10:26 AM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Corr, Elizabeth <Corr.Elizabeth@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>
Subject: 10/26 Meeting on EPA-FDA Fish Advice

Kacee,

Hi. Would it be possible to shift the time for the 10/26 EPA-FDA Fish Advice meeting to enable Joel to join? Currently, we could reschedule for pretty much any time that day with the exception of 10:50 - 11:30, as Joel is scheduled to speak at an ECOS Officers meeting. Would it

be possible to bump the EPA-FDA Fish Advice meeting back 15 minutes to 10:00 to 10:40? If the meeting can't be moved, we can leave the meeting, as scheduled, with Betsy, as we don't want to push the meeting out further on the calendar. If there are questions, please let me know. Thank you!

Karen Gude, Special Assistant
U.S. Environmental Protection Agency
Office of Water
Phone: (202) 564-0831

Subject: EPA-FDA Fish Advice
Location: 41209 RRB

Start: Wed 10/26/2016 10:15 AM
End: Wed 10/26/2016 11:00 AM

Recurrence: (none)

Meeting Status: Accepted

Organizer: Burke, Thomas
Required Attendees: Deener, Kathleen; Flowers, Lynn; Southerland, Elizabeth; Larimer, Lisa

Kacee suggested I contact you to set up a meeting with Dr. Burke. We would like to have it, if possible, the week of Oct. 17 or 24. The invitees would be:

From ORD - Tom Burke, Kacee Deener, Lynn Flowers
From OW - Elizabeth (Betsy) Southerland, Lisa Larimer

One hour should be sufficient. To help with scheduling Betsy Southerland, I suggest you contact Jeanette Martin, 202-566-0984.

Please let me know of any additional information you may need.

Thanks,
Lisa

Lisa Larimer, P.E. | Team Leader
U.S. Environmental Protection Agency | Washington, DC
Office of Water | Standards and Health Protection Division
☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Burke, Thomas
Sent: Thur 12/17/2015 11:29:57 PM
Subject: Fwd: Administrator McCarthy cc'ed on Letter to Dr. Ostroff re: Seafood Advice
121715 Seafood Advice[redacted].pdf
ATT00001.htm

Ex. 5 - Deliberative Process

Thomas A. Burke, PhD, MPH
Deputy Assistant Administrator
EPA Science Advisor
Office of Research and Development
202-564-6620
burke.thomas@epa.gov

Begin forwarded message:

From: "Beauvais, Joel" <Beauvais.Joel@epa.gov>
Date: December 17, 2015 at 5:29:28 PM EST
To: "Burke, Thomas" <Burke.Thomas@epa.gov>
Subject: FW: Administrator McCarthy cc'ed on Letter to Dr. Ostroff re: Seafood Advice

FYI

From: Borum, Denis
Sent: Thursday, December 17, 2015 2:57 PM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>; Beauvais, Joel <Beauvais.Joel@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Peck, Gregory <Peck.Gregory@epa.gov>
Cc: Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Orvin, Chris <Orvin.Chris@epa.gov>
Subject: Administrator McCarthy cc'ed on Letter to Dr. Ostroff re: Seafood Advice

All,

Please see attached letter from Senators Murray plus 29, regarding FDA advice on seafood consumption for pregnant women. The letter is addressed to Dr. Ostroff at FDA, but Gina

McCarthy is cc:ed. Just an FYI for us. I had brought this up a week ago at the OW Weekly management meeting f

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Denis

Denis R. Borum

Congressional Liaison Specialist

Office of Congressional and Intergovernmental Relations

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, N.W. (MC-1301A)

Washington, D.C. 20460

(202) 564-4836 (phone)

(202) 501-1549 (fax)

borum.denis@epa.gov (e-mail)

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Burke, Thomas
Sent: Wed 12/9/2015 11:15:21 AM
Subject: Fwd: Fish advice - remaining issues for staff level discussion
Ex. 5 - Deliberative Process fish advice 12-8-15.docx
ATT00001.htm

Thomas A. Burke, PhD, MPH
Deputy Assistant Administrator
EPA Science Advisor
Office of Research and Development
202-564-6620
burke.thomas@epa.gov

Begin forwarded message:

From: "Beauvais, Joel" <Beauvais.Joel@epa.gov>
Date: December 8, 2015 at 10:25:39 PM EST
To: "Burke, Thomas" <Burke.Thomas@epa.gov>
Subject: Fish advice - remaining issues for staff level discussion

Tom - I have not yet heard anything back from FDA following our meeting; will let you know when I do. In the meantime, FDA had asked that we reconvene the staff working group Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Joel

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: D'Amico, Louis
Sent: Fri 9/30/2016 12:51:26 PM
Subject: RE: Supplemental information for Tom on fish/mercury

Damn it. Process, not progress. Must have typed too fast. Sorry!

My understanding was basically that Tom wanted the papers to be able to show to Ex. 5 - Deliberative Process I assume a top level bullet boiling down what a specific paper says about Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process is sufficient.

Louis D'Amico, Ph.D.

Acting Communications Director, ORD/NCEA

damico.louis@epa.gov

O: (703) 347-0344 M: (703) 859-1719

From: Deener, Kathleen
Sent: Friday, September 30, 2016 8:09 AM
To: D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: Re: Supplemental information for Tom on fish/mercury

What are the progress bullets? I must have missed something.

Sent from my iPhone

On Sep 29, 2016, at 6:19 PM, D'Amico, Louis <DAmico.Louis@epa.gov> wrote:

> Hi Kacee,
>
> I'll talk to Linda tomorrow and see what we can come up with along with the progress bullets. Thanks!

-Lou

Louis D'Amico, Ph.D.

Acting Communications Director, ORD/NCEA

damico.louis@epa.gov

O: (703) 347-0344 M: (703) 859-1719

From: Deener, Kathleen
Sent: Thursday, September 29, 2016 5:34 PM
To: Ross, Mary <Ross.Mary@epa.gov>; Slimak, Michael <Slimak.Michael@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>
Cc: Corona, Elizabeth <Corona.Elizabeth@epa.gov>; Gwinn, Maureen <gwinn.maureen@epa.gov>
Subject: Supplemental information for Tom on fish/mercury

Hi Folks –

At the end of the today's meeting on fish and mercury, Tom asked for a few items.

1. The current version of the EPA/FDA fish consumption advice chart (attached – this is a post-peer review draft version)

2 **Ex. 5 - Deliberative Process**
(t

I've attached three documents that might be helpful for #2 – **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Feel free to use the information I attached (it was stuff I had on hand already), but I was thinking perhaps Linda Phillips might have some information also. Let me know if you don't think you'll be able to do this by COB Monday (which is when we will need it).

Thanks!

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

To: Beauvais, Joel[Beauvais.Joel@epa.gov]
From: Burke, Thomas
Sent: Thur 12/3/2015 1:34:28 AM
Subject: Fwd: Fish advice table
Ex. 5 - Deliberative Process fish advice-120215__TB.docx
ATT00001.htm

Joel,

Sorry, I have been tied up throughout the day and just got home. Attached is my attempt at revisions. They are minor and aimed to provide flexibility and clarity.

Ex. 5 - Deliberative Process

Available now, Let me know if you want to discuss. We could also get together tomorrow for a brief prep time before the meeting.

Tom

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Kime, Robin
Sent: Mon 9/28/2015 2:29:43 PM
Subject: FDA-EPA Fish Advisory

Hi

I checked in with folks here and the FDA-EPA Fish Advisory meeting isn't on our radar at the moment. If there is something you'd like me to pass along here to pave the way for this conversation, just let me know. Thanks and take care.

Robin

564-6587

From: Smith, Kelley
Sent: Monday, September 28, 2015 10:09 AM
To: Kime, Robin
Cc: Gentry, Nathan; Deener, Kathleen
Subject: RE: Ex. 5 - Deliberative Process DRAFT 9 22 15

We will keep it as scheduled.

As an FYI- Dr. Burke is interested in talking to Joel about a recent FDA-EPA Fish Advisory

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process She should be able to give you a little more background if needed prior to Joel and Tom connecting.

Best,

KS

Kelley Smith

Program Advisor

Office of Research and Development

Environmental Protection Agency

202.564.2308 (Desk)

202.308.6587 (Cell)

Smith.Kelley@epa.gov

From: Kime, Robin
Sent: Monday, September 28, 2015 9:23 AM
To: Smith, Kelley <Smith.Kelley@epa.gov>
Cc: Gentry, Nathan <Gentry.Nathan@epa.gov>
Subject: FW: Ex. 5 - Deliberative Process DRAFT 9 22 15

Hi- This is the topic of the call tomorrow. Thx

From: Beauvais, Joel
Sent: Tuesday, September 22, 2015 10:15 AM
To: Burke, Thomas
Cc: McGartland, Al; Dockins, Chris
Subject: Ex. 5 - Deliberative Process DRAFT 9 22 15

Ex. 5 - Deliberative Process

Tom – As we discussed at our one-on-one, we would like to send out a memo to AAs soon, launching a collaborative effort to Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process If you're amenable, we would welcome any input you have on substance. If that doesn't make sense, we will edit to send out from me alone, referencing opportunities for ORD collaboration.

I am eager to get this off the ground, given the limited time horizon of the current administration, so if you could get back to me on this in the near future, I'd be grateful. Al, Chris and company are happy to sit down with your staff to talk specifics if that would be helpful.

Joel

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Burke, Thomas
Sent: Sat 9/26/2015 3:12:57 PM
Subject: Re: Ex. 5 - Deliberative Process fish advice

Thanks Kacee. Look forward to discussing.

Tom

Thomas A. Burke, PhD, MPH
Deputy Assistant Administrator
EPA Science Advisor
Office of Research and Development
202-564-6620
burke.thomas@epa.gov

On Sep 26, 2015, at 9:16 AM, Deener, Kathleen <Deener.Kathleen@epa.gov> wrote:

> FYI
>
> Sent from my iPhone
>
> Begin forwarded message:
>
> **From:** "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
> **Date:** September 26, 2015 at 8:42:53 AM EDT
> **To:** "Hisel-Mccoy, Sara" <Hisel-McCoy.Sara@epa.gov>
> **Cc:** "Larimer, Lisa" <Larimer.Lisa@epa.gov>, "Barash, Shari" <Barash.Shari@epa.gov>, "Wathen, John" <Wathen.John@epa.gov>, "Deener, Kathleen" <Deener.Kathleen@epa.gov>, "Hauchman, Fred" <hauchman.fred@epa.gov>
> **Subject: Re:** Ex. 5 - Deliberative Process **fish advice**
>
> I sent this on. Ex. 5 - Deliberative Process
>
> **Ex. 5 - Deliberative Process**
>
> Sent from my iPhone
>
> On Sep 25, 2015, at 6:38 PM, Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov> wrote:

Thank you so much, Lisa. Betsy-as you requested.

Sara Hisel-McCoy
Standards and Health Protection Division
202 566-1649

On Sep 25, 2015, at 5:49 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

In the table below I'm showing the mercury concentrations by fish type Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

FINFISH/SHELLFISH	Mean Hg conc (ppm)
ANCHOVIES	0.02
BLUEFISH	0.37
BUFFALO FISH	0.14
CARP	0.11
CATFISH	0.02
CLAM	0.01
COD	0.11
CRAB	0.06
CRAWFISH	0.03
CROAKER, ATLANTIC	0.07
CROAKER, WHITE	0.29
FLATFISH: FLOUNDER	0.05
FLATFISH: PLAICE	0.04
FLATFISH: SOLE	0.08
GROUPER	0.45
HADDOCK	0.06
HAKE	0.08

Ex. 5 - Deliberative Process

HALIBUT	0.24
HERRING	0.08
LOBSTER, AMERICAN	0.11
LOBSTER, SPINY	0.09
MAHI MAHI	0.18
MARLIN	0.49
MONKFISH	0.16
MULLET	0.05
ORANGE ROUGHY	0.57
OYSTER	0.01
PERCH, FRESHWATER	0.15
PERCH, OCEAN	0.12
PICKEREL	0.09
POLLOCK	0.03
ROCKFISH	0.23
SABLE FISH	0.36
SALMON	0.02
SALMON, CANNED	0.01
SARDINE	0.01
SCALLOP	0.00
SCORPIONFISH	0.23
SEA BASS, BLACK	0.13
SEA BASS, CHILEAN	0.35
SEA BASS, STRIPED	0.07
SHAD	0.04
SHEEPSHEAD	0.09
SHRIMP	0.01
SMELT	0.08
SNAPPER	0.17
SQUID	0.02
SWORDFISH	1.00
TILAPIA	0.01
TILEFISH, ATLANTIC	0.14
TROUT, FRESHWATER	0.07
TUNA, CANNED (ALBACORE)	0.35
TUNA, CANNED (LIGHT)	0.13
TUNA, FR/FZN ALBACORE	0.36
TUNA, FR/FZN BIGEYE	0.69
TUNA, FR/FZN SKIPJACK	0.14
TUNA, FR/FZN YELLOWFIN	0.35
WEAKFISH (SEA	

Ex. 5 - Deliberative Process

TROUT)	
WHITEFISH	0.09
WHITING	0.05

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Burke, Thomas
Sent: Tue 12/1/2015 7:58:29 PM
Subject: Fwd: Revised terms for fish advice
Terms for fish advice-120115.docx
ATT00001.htm
FISH_CHART_H_11 30.pdf
ATT00002.htm

Let's get to editing based on our discussion

Thomas A. Burke, PhD, MPH
Deputy Assistant Administrator
EPA Science Advisor
Office of Research and Development
202-564-6620
burke.thomas@epa.gov

Begin forwarded message:

From: "Beauvais, Joel" <Beauvais.Joel@epa.gov>
Date: December 1, 2015 at 2:54:03 PM EST
To: "Burke, Thomas" <Burke.Thomas@epa.gov>
Subject: Revised terms for fish advice

Tom – Following up on our conversation Monday, I am sending along two attachments.

The first is a revised version of the Advice chart that FDA sent this week to OW staff. It reflects changes that FDA has made in response to NIH comments and internal focus testing. In brief, the changes they have already made in the draft are as follows:

Ex. 5 - Deliberative Process

The Word document I'm attaching is a revised version of Ex. 5 - Deliberative Process for the Thursday discussion. This has been revised to account both for FDA's new draft and my understanding of your suggestions on our Monday call. Please let me know if this works for you, or if not, please provide line edits so we can finalize before meeting on Thursday.

Here's a summary of the changes made to the term sheet since our discussion Monday:

Ex. 5 - Deliberative Process

Joel

To: Beauvais, Joel[Beauvais.Joel@epa.gov]
Cc: Burke, Thomas[Burke.Thomas@epa.gov]; Gentry, Nathan[Gentry.Nathan@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]; Penman, Crystal[Penman.Crystal@epa.gov]; Bethel, Heidi[Bethel.Heidi@epa.gov]
From: Southerland, Elizabeth
Sent: Wed 11/11/2015 1:34:56 AM
Subject: Re: fish advice meeting

Definitely provide a phone number so I can call in for the meeting. Thanks!

Sent from my iPhone

On Nov 10, 2015, at 6:26 PM, Beauvais, Joel <Beauvais.Joel@epa.gov> wrote:

> Great – thanks, Tom. Crystal, see below on the meeting I asked to set up – let's make this happen this Friday.
>
> Joel
>
> **From:** Burke, Thomas
> **Sent:** Tuesday, November 10, 2015 6:25 PM
> **To:** Beauvais, Joel <Beauvais.Joel@epa.gov>
> **Cc:** Gentry, Nathan <Gentry.Nathan@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>
> **Subject:** Re: fish advice meeting
>
> Let's aim for Friday the 13th. I will ask Nathan and Kacee to coordinate with your office.
>
> Tom
>
> Thomas A. Burke, PhD, MPH
>
> Deputy Assistant Administrator
>
> EPA Science Advisor
>
> Office of Research and Development

202-564-6620

burke.thomas@epa.gov

On Nov 10, 2015, at 6:04 PM, Beauvais, Joel <Beauvais.Joel@epa.gov> wrote:

> Tom – Is there any chance at all that we can make this happen this Thursday or Friday instead of having to wait until Thursday of next week? Ex. 5 - Deliberative Process
>
> Ex. 5 - Deliberative Process
>
> Joel

To: Beauvais, Joel[Beauvais.Joel@epa.gov]
Cc: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Burke, Thomas
Sent: Mon 11/9/2015 11:20:26 AM
Subject: Re: Fish Advice

Will do and happy to be part of the discussions if I can assist.

Tom

Thomas A. Burke, PhD, MPH
Deputy Assistant Administrator
EPA Science Advisor
Office of Research and Development
202-564-6620
burke.thomas@epa.gov

> On Nov 8, 2015, at 9:44 PM, Beauvais, Joel <Beauvais.Joel@epa.gov> wrote:
>
> Hi Tom - Ken did not connect with FDA before departing so I am picking this up. I am getting briefed by OW staff tomorrow and will be talking to the Deputy Commissioner for Policy at FDA within the next couple days. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

> Joel

From: Gentry, Nathan
Location: DCRoomRRB41213/ORD
Importance: Normal
Subject: EPA-FDA Fish Advice
Start Date/Time: Mon 8/17/2015 8:00:00 PM
End Date/Time: Mon 8/17/2015 8:30:00 PM
EPA FDA fish advice 2015 v2.docx
att 3 2015 FISH_CHART.PDF

POC: Rita Schoeny

Rita expects Tom to be invited to a briefing for the Administrator on this topic soon.

To: Gentry, Nathan[Gentry.Nathan@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Schoeny, Rita
Sent: Fri 8/14/2015 3:52:18 PM
Subject: RE: EPA-FDA Fish Advice

Yes . Out today, but Kacee should have one word doc and a PDF to send you. Or I'll send from home computer tonight.

Sent from my Windows Phone

From: Gentry, Nathan
Sent: 8/14/2015 11:01 AM
To: Schoeny, Rita
Subject: RE: EPA-FDA Fish Advice

Any materials for this?

Nathan Gentry
Scheduler for Tom Burke, Lek Kadeli and Bob Kavlock
EPA Office of Research and Development
Phone: 202-564-9084
Fax: 202-565-2430

-----Original Appointment-----
From: Gentry, Nathan **On Behalf Of** Burke, Thomas
Sent: Thursday, August 13, 2015 9:33 AM
To: Burke, Thomas; Kavlock, Robert; Schoeny, Rita; Cantilli, Robert; Fegley, Robert; Hauchman, Fred; Gwinn, Maureen; Deener, Kathleen; Smith, Kelley
Subject: EPA-FDA Fish Advice
When: Monday, August 17, 2015 4:00 PM-4:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomRRB41213/ORD

POC: Rita Schoeny

Rita expects Tom to be invited to a briefing for the Administrator on this topic soon.

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Schoeny, Rita
Sent: Thur 8/13/2015 1:00:41 PM
Subject: RE: Material for Tom B on fish advice

So, will you arrange 30 minutes, or should I get on the phone with Nathan? Thanks.

From: Deener, Kathleen
Sent: Wednesday, August 12, 2015 7:04 PM
To: Schoeny, Rita; Cantilli, Robert; Fegley, Robert; Hauchman, Fred
Cc: Gwinn, Maureen; Smith, Kelley
Subject: RE: Material for Tom B on fish advice

Hi All – I've chatted with folks here, and I think it would be a good idea to brief Tom and Bob on this one (since the Administrator will be briefed and could potentially ask Tom about this).

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Schoeny, Rita
Sent: Wednesday, August 12, 2015 4:18 PM
To: Deener, Kathleen; Cantilli, Robert; Fegley, Robert; Hauchman, Fred
Cc: Gwinn, Maureen
Subject: RE: Material for Tom B on fish advice

Hi. Accepted all your edits. In answer to questions –

Ex. 5 - Deliberative Process

Talk to you later.

From: Deener, Kathleen
Sent: Wednesday, August 12, 2015 3:01 PM
To: Schoeny, Rita; Cantilli, Robert; Fegley, Robert; Hauchman, Fred
Cc: Gwinn, Maureen
Subject: RE: Material for Tom B on fish advice

Hi Rita – This looks great – thanks for sharing! I've offered a few very minor edits and I asked a few questions. See attached.

Is OSP planning to brief the IOAA on this – or just share the written briefing materials? Adding Maureen since I assume Bob K. will be part of any briefing.

Thanks,

Kacee Deener, MPH

Senior Science Advisor

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deener.kathleen@epa.gov

From: Schoeny, Rita
Sent: Tuesday, August 11, 2015 4:20 PM
To: Deener, Kathleen; Cantilli, Robert; Fegley, Robert; Hauchman, Fred
Subject: Material for Tom B on fish advice

Hi, all. Check this out, and let me know of changes. There is a lot of convoluted history that we don't necessarily need to present.

Rita Schoeny, Ph.D.
Senior Science Advisor, Office of Science Policy
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U.S. Environmental Protection Agency
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1200 Pennsylvania Avenue NW (8104R)
Washington DC 20460-0001

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Address for delivery:
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Washington DC 20004

To: Deener, Kathleen[Deener.Kathleen@epa.gov]
Cc: Phillips, Linda[Phillips.Linda@epa.gov]; Ross, Mary[Ross.Mary@epa.gov]; Birchfield, Norman[Birchfield.Norman@epa.gov]
From: Bussard, David
Sent: Mon 10/26/2015 1:38:30 PM
Subject: information on Hg and fish for today's discussion - printable versions
spreadsheet explanation 10-20-15_v2.docx
Example Calculations 10-20-15-rev_printable.xlsx

Kacee,

Should anyone want it, attached in the original explanation Lynn sent you, and a revised spreadsheet that has the Tabs formatted so that they print more easily.

David

From: Flowers, Lynn
Sent: Tuesday, October 20, 2015 12:12 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; Phillips, Linda <Phillips.Linda@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>
Subject: information on Hg and fish for today's discussion

Kacee:

There are two attachments for today's check in meeting with you:

1) A spreadsheet of calculations as requested (note that there are two tabs), and

2) A write up of the analysis and results.

I also have a short list of issues to note:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lynn Flowers, PhD, DABT

Associate Director for Health

National Center for Environmental Assessment

US EPA

Washington, DC

703-347-8537

To: Burke, Thomas[Burke.Thomas@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Kavlock, Robert
Sent: Tue 1/12/2016 11:06:58 PM
Subject: fish

News Headline: FEDERAL DIETARY GUIDELINES ENCOURAGE LOW-MERCURY FISH CONSUMPTION |

News Date: 01/12/2016
Outlet Full Name: Risk Policy Report
Contact Name:
News Text: Newly released federal dietary guidelines encourage the public to increase its consumption of fish while also for the first time informing that fish species vary in the levels of beneficial oils and harmful methylmercury they contain, picking up on draft advice EPA and the Food and Drug Administration (FDA) issued in 2014.

The finalized Dietary Guidelines for Americans (DGA), released Jan. 7, largely sidesteps the controversial advice an advisory panel gave to the Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA), where the advisors urged HHS and USDA to encourage EPA and FDA to reconsider their draft advice on tuna consumption. Tuna is one of the most commonly eaten fish in the U.S.

Instead, the DGA, which supersedes other federal guidance, repeats its 2010 advice, which for the first time set a floor for the amount of fish that Americans should eat on a weekly basis. The latest report reiterates that pregnant women, should eat no less than 8 ounces of fish per week, while not exceeding 12 ounces of fish per week.

New however, is the DGA's recognition that different seafood species contain different levels of methylmercury and varying amounts of beneficial oils. "For the general population, consumption of about 8 ounces per week of a variety of seafood, which provide an average consumption of 250 mg per day of [eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)], is associated with reduced cardiac deaths among individuals with and without preexisting [cardiovascular disease]," the DGA advises. "Similarly, consumption by women who are pregnant or breastfeeding of at least 8 ounces per week from seafood choices that are sources of DHA is associated with improved infant health outcomes."

The DGA continues by noting that "[w]omen who are pregnant or breastfeeding should consume at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in methylmercury. Obstetricians and pediatricians should provide guidance on how to make healthy food choices that include seafood. Women who are pregnant or breastfeeding and young children should not eat certain types of fish that are high in methylmercury."

The guidelines simplify the 2014 draft advisory from EPA and FDA that sought to balance EPA's traditional concerns that fish can be contaminated with methylmercury, a neurotoxin particularly potent to the developing fetus, with FDA's efforts to encourage women to eat more fish because the lean protein provides beneficial oils like Omega 3s and DHA that boost brain and eye development in the fetus.

The DGA, issued by HHS and USDA, is aimed at broadly advising all Americans on how to eat a healthy diet. It is also used to establish public school lunch menus and which foods are covered as part of federal consumer food subsidy programs.

Last year the Dietary Guidelines Advisory Committee (DGAC) suggested, based on FDA modeling, that EPA and FDA could increase the amount of albacore tuna that would be safe for these women to eat up to six ounces per week -- advice that horrified environmentalists and public health groups concerned with the amounts of mercury albacore tuna.

At a hearing last March, for example, William Wallace of Consumers Union urged the committee to recommend that EPA and FDA advise "that pregnant women eat no tuna." And in a June statement, several groups argued the DGAC's advice on consumption of albacore tuna would pose risks to children.

Tuna "is by far the largest source of mercury in the American diet, accounting for an estimated 45 percent of all mercury exposure," the groups said. "Albacore tuna has three times more mercury than light tuna and is therefore an unhealthy choice for pregnant women and children."

By contrast, the tuna industry at the March hearing reiterated the DGAC's advice, and some 29 senators in a letter to the FDA Commissioner Stephen Ostroff last April also encouraged reconsidering the albacore tuna limit, based on the DGAC's report.

The latest DGA does not list any species to avoid, as EPA and FDA do, but it does cite the general principles of those agencies' advice.

For the first time, the DGA lists specific types of seafood to recommend as high in beneficial oils and low in mercury -- not including any kind of tuna. "Seafood choices higher in EPA and DHA but lower in methylmercury are encouraged. Seafood varieties commonly consumed in the United States that are higher in EPA and DHA and lower in methylmercury include salmon, anchovies, herring, shad, sardines, Pacific oysters, trout, and Atlantic and Pacific mackerel (not king mackerel, which is high in methylmercury)."

A source with the Environmental Working Group cautiously praised the new advice. The DGA "gives some idea of the complexity to seafood advice, notably the best things [to eat] . . . it's a good list and it doesn't include tuna," the source says. "Some of it is so basic [what we've asked for and that] EPA and FDA avoided doing."

The source compared the DGA advice favorably to the 2014 draft advisory from EPA and FDA. "Compared to the EPA-FDA advice, this is an improvement," the source said. "It conveys some of the differences in the fish species. It gives a clear list [of recommended fish] and clear advice on numerical [limits]. But, the source adds, the advice is "weak on mercury," noting that it does not provide a list of fish to avoid.

The fishing industry is also touting the new DGA advice, though it also does not mention tuna. "When it comes to seafood the DGA's are clear -- seafood is called out over and over again as a food to encourage," a spokesman for the National Fisheries Institute says. "The DGA's do call for Americans to eat at least 8 [ounces] of fish per week to get the benefits but they also call on pregnant women to eat 8-12 ounces. This is significant because the FDA reports that currently pregnant women eat only 1.89 [ounces] a week, which means now they're missing out on the benefits of seafood." -- Maria Hegstad

To: Kime, Robin[Kime.Robin@epa.gov]
Cc: Gentry, Nathan[Gentry.Nathan@epa.gov]; Deener, Kathleen[Deener.Kathleen@epa.gov]
From: Smith, Kelley
Sent: Mon 9/28/2015 2:08:36 PM
Subject: RE: Ex. 5 - Deliberative Process RD DRAFT 9 22 15
Ex. 5 - Deliberative Process DRAFT 9 22 15.docx

We will keep it as scheduled.

As an FYI- Dr. Burke is interested in talking to Joel about a recent FDA-EPA Fish Advisory meeting he had with the Administrator. I don't believe OP was involved in this OW / FDA effort but he is interested in advice from some OP staff on the effort. My colleague Kacee (cc'd) has been running point on this and may have already contacted D. Axelrod and A. McGartland. She should be able to give you a little more background if needed prior to Joel and Tom connecting.

Best,

KS

Kelley Smith

Program Advisor

Office of Research and Development

Environmental Protection Agency

202.564.2308 (Desk)

202.308.6587 (Cell)

Smith.Kelley@epa.gov

From: Kime, Robin
Sent: Monday, September 28, 2015 9:23 AM
To: Smith, Kelley <Smith.Kelley@epa.gov>

Cc: Gentry, Nathan <Gentry.Nathan@epa.gov>
Subject: FW: Ex. 5 - Deliberative Process 9 22 15

Hi- This is the topic of the call tomorrow. Thx

From: Beauvais, Joel
Sent: Tuesday, September 22, 2015 10:15 AM
To: Burke, Thomas
Cc: McGartland, Al; Dockins, Chris
Subject: Health Benefits memo OP-ORD DRAFT 9 22 15

Tom – As we discussed at our one-on-one, we would like to send out a memo to AAs soon, launching a collaborative effort Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

I am eager to get this off the ground, given the limited time horizon of the current administration, so if you could get back to me on this in the near future, I'd be grateful. Al, Chris and company are happy to sit down with your staff to talk specifics if that would be helpful.

Joel

To: Corona, Elizabeth[Corona.Elizabeth@epa.gov]
From: Deener, Kathleen
Sent: Tue 5/3/2016 9:58:00 PM
Subject: FW: Request to meet about seafood advice for pregnant women
EWG_MercuryinSeafood.pdf
ATT00001.htm

To add to the pile.

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

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deener.kathleen@epa.gov

From: Sinks, Tom
Sent: Tuesday, May 03, 2016 5:38 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Subject: Fwd: Request to meet about seafood advice for pregnant women

FYI. I'm happy to meet with EWG They have a long track record of biomomitoring using convenience sampling. My personal opinion is we should meet with them and invite other program offices and OCH.

Sent from my iPhone

Begin forwarded message:

> **From:** "Christine Hill" <christine@ewg.org>
> **To:** "Burke, Thomas" <Burke.Thomas@epa.gov>, "Sinks, Tom" <Sinks.Tom@epa.gov>
> **Cc:** "sonya@ewg.org" <sonya@ewg.org>
> **Subject: Request to meet about seafood advice for pregnant women**
>
> Good Afternoon,
>
> I hope this email finds you well.

In March, the Environmental Working Group released a report that tested hair mercury levels for 254 women who eat 2 or more seafood meals per week. We found that 29 percent of participants had hair mercury levels >= 1 part per million, roughly equivalent to EPA's reference dose.

Further, only 17% of estimated mercury ingestion was from the species presently named in the FDA/EPA seafood advice, and that tuna (steaks, sushi, and canned albacore and light) made up 40% of the mercury in our study participants' diets. The report is attached and Sonya Lunder, the author of the report, is CC'ed on this email for any follow up questions.

EWG has long been concerned about the EPA/ FDA seafood advice for pregnant women.

Would it be possible to arrange a meeting in the next few weeks to discuss our study findings and ongoing concerns about the draft seafood advice for pregnant women?

Please let me know.

Thanks,

Chris

—

Christine M. Hill
Director, Government Affairs
EWG | www.ewg.org<http://www.ewg.org/>
1436 U St. N.W. Suite 100
Washington, DC 20009
O: 202-939-9125 | C: 240-338-0987
E: Chill@ewg.org<mailto:Chill@ewg.org>

From: Deener, Kathleen
Location: 41209 RRB
Importance: Normal
Subject: EPA-FDA Fish Advice
Start Date/Time: Wed 10/26/2016 2:15:00 PM
End Date/Time: Wed 10/26/2016 3:00:00 PM

Kacee suggested I contact you to set up a meeting with Dr. Burke. We would like to have it, if possible, the week of Oct. 17 or 24. The invitees would be:

From ORD - Tom Burke, Kacee Deener, Lynn Flowers
From OW - Elizabeth (Betsy) Southerland, Lisa Larimer

One hour should be sufficient. To help with scheduling Betsy Southerland, I suggest you contact Jeanette Martin, 202-566-0984.

Please let me know of any additional information you may need.

Thanks,
Lisa

Lisa Larimer, P.E. | Team Leader
U.S. Environmental Protection Agency | Washington, DC
Office of Water | Standards and Health Protection Division
☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Smith, Kelley[Smith.Kelley@epa.gov]
From: Deener, Kathleen
Sent: Wed 11/18/2015 10:52:37 PM
Subject: Re: Briefing Book for Tomorrow

Sounds good. Thanks Kelley!

Sent from my iPhone

On Nov 18, 2015, at 5:41 PM, Smith, Kelley <Smith.Kelley@epa.gov> wrote:

> Yes- I anticipated that he would need some time to prep for the WH mtg and the fish meeting with the administrator.
>
> 1030-1 is open and is held as office work time / lunch
>
> We can ask tom if he is ok with us using some of that time in our 9am.
>
> Best,
>
> KS
>
> Kelley Smith
>
> Program Advisor
>
> Office of Research and Development
>
> Environmental Protection Agency
>
> 202.564.2308 (Desk)
>
> 202.308.6587 (Cell)
>
> Smith.Kelley@epa.gov

From: Deener, Kathleen
Sent: Wednesday, November 18, 2015 5:03 PM
To: Smith, Kelley <Smith.Kelley@epa.gov>
Subject: Re: Briefing Book for Tomorrow

Kelley - just FYI, I'm going over to the tire crumb meeting with Tom.

Also - is there any small window of time when Tom, Fred and I could huddle before the WH meeting? I can't really see his calendar from my iPhone.

Thanks!

Kacee

Sent from my iPhone

On Nov 18, 2015, at 4:58 PM, Smith, Kelley <Smith.Kelley@epa.gov> wrote:

> Good Afternoon Tom,
>
> I hope your flight back to Baltimore went well! I wanted to reach out to flag that your briefing materials for tomorrow are in the google drive and your binder will be at your desk when you arrive tomorrow morning. In addition there are two meetings of note tomorrow that I have listed below.
>
> Do you need Kacee or I to put together any last min items for either meeting?
>
> 1:30 – 2:00 PM **Fish Advice Meeting**
>
> *Attendees:* Administrator, Joel Beauvais, and you

Note: This meeting was at a different date but was moved up per Nathan.

3:00 – 4:00 PM **Artificial Turf/Tire Crumb Action Plan mtg at the WH**

HHS: Anne Reid, Pat Breysse

EPA: Tom Burke, Fred Hauchman, Jeff Morris

CPSC: Patricia Adkins, Jay Howell

EOP: Carole Johnson, Candace Vahlsing, Bruce Rodan, Drew McConville, Chinyere Ekechi

Note: Briefing materials are in the google drive and are in your binder.

Best,

KS

Kelley Smith

Program Advisor

Office of Research and Development

Environmental Protection Agency

202.564.2308 (Desk)

202.308.6587 (Cell)

Smith.Kelley@epa.gov

To: D'Amico, Louis[DAmico.Louis@epa.gov]
From: Deener, Kathleen
Sent: Fri 9/30/2016 12:54:05 PM
Subject: RE: Supplemental information for Tom on fish/mercury

Yes – that would be perfect. Just a few bullets highlighting Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process I can do it if needed – but I thought Linda might be able to quickly pull it together given her knowledge of this issue (or maybe Jackie).

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

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deener.kathleen@epa.gov

From: D'Amico, Louis
Sent: Friday, September 30, 2016 8:51 AM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Subject: RE: Supplemental information for Tom on fish/mercury

Damn it. Process, not progress. Must have typed too fast. Sorry!

My understanding was basically that Tom wanted the papers to be able to show to the IG staff. I assume a top level bullet boiling down what a specific paper says Ex. 5 - Deliberative Process Ex. 5 - Deliberative Process is sufficient.

Louis D'Amico, Ph.D.

Acting Communications Director, ORD/NCEA

damico.louis@epa.gov

O: (703) 347-0344 M: (703) 859-1719

From: Deener, Kathleen
Sent: Friday, September 30, 2016 8:09 AM
To: D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: Re: Supplemental information for Tom on fish/mercury

What are the progress bullets? I must have missed something.

Sent from my iPhone

On Sep 29, 2016, at 6:19 PM, D'Amico, Louis <DAmico.Louis@epa.gov> wrote:

> Hi Kacee,
>
> I'll talk to Linda tomorrow and see what we can come up with along with the progress bullets. Thanks!
>
> -Lou
>
> Louis D'Amico, Ph.D.
>
> Acting Communications Director, ORD/NCEA
>
> damico.louis@epa.gov
>
> O: (703) 347-0344 M: (703) 859-1719

From: Deener, Kathleen
Sent: Thursday, September 29, 2016 5:34 PM
To: Ross, Mary <Ross.Mary@epa.gov>; Slimak, Michael <Slimak.Michael@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>
Cc: Corona, Elizabeth <Corona.Elizabeth@epa.gov>; Gwinn, Maureen <gwinn.maureen@epa.gov>
Subject: Supplemental information for Tom on fish/mercury

Hi Folks –

At the end of the today's meeting on fish and mercury, Tom asked for a few items.

1. The current version of the EPA/FDA fish consumption advice chart (attached – this is a post-peer review draft version)

2. Information on Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

I've attached three documents that might be helpful for #2 – Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

Would NCEA be able to put together a few bullets for Tom about Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process Feel free to use the information I attached (it was stuff I had on hand already), but I was thinking perhaps Linda Phillips might have some information also. Let me know if you don't think you'll be able to do this by COB Monday (which is when we will need it).

Thanks!

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

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deener.kathleen@epa.gov

To: Burke, Thomas[Burke.Thomas@epa.gov]
From: Deener, Kathleen
Sent: Wed 12/2/2015 11:41:20 PM
Subject: FW: updated fish document
Ex. 5 - Deliberative Process 12.2.15.docx

Tom – Just re-sending this since I know you've been offline for the afternoon. I saw in your email that Joel is asking about this document (he sent an email about an hour ago).

Let me know if you need anything else from me on this. I'm still at the office but planning to pack up and head home in the next 15-20 minutes.

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

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deener.kathleen@epa.gov

From: Deener, Kathleen
Sent: Wednesday, December 02, 2015 9:55 AM
To: Burke, Thomas <Burke.Thomas@epa.gov>
Subject: updated fish document

Hi Tom –

Here's the updated fish document with edits from Tom S, Lynn Flowers, and Linda Phillips. Let me know if you think additional changes are needed.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Kacee Deener, MPH

Senior Science Advisor

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deener.kathleen@epa.gov

A Biomonitoring Study of Lead, Cadmium, and Mercury in the Blood of New York City Adults

Wendy McKelvey,[1] R. Charon Gwynn,[2] Nancy Jeffery,[1] Daniel Kass,[1] Lorna E. Thorpe,[2] Renu K. Garg,[2] Christopher D. Palmer,[3] and Patrick J. Parsons[3,4]

[1]Division of Environmental Health, and [2]Division of Epidemiology, New York City Department of Health and Mental Hygiene, New York, New York, USA; [3]Trace Elements Laboratory, Wadsworth Center, New York State Department of Health, Albany, New York, USA; [4]Department of Environmental Health Sciences, School of Public Health, University at Albany, State University of New York, Albany, New York, USA

Objectives: We assessed the extent of exposure to lead, cadmium, and mercury in the New York City (NYC) adult population.

Methods: We measured blood metal concentrations in a representative sample of 1,811 NYC residents as part of the NYC Health and Nutrition Examination Survey, 2004.

Results: The geometric mean blood mercury concentration was 2.73 μg/L [95% confidence interval (CI), 2.58–2.89]; blood lead concentration was 1.79 μg/dL (95% CI, 1.73–1.86); and blood cadmium concentration was 0.77 μg/L (95% CI, 0.75–0.80). Mercury levels were more than three times that of national levels. An estimated 24.8% (95% CI, 22.2–27.7%) of the NYC adult population had blood mercury concentration at or above the 5 μg/L New York State reportable level. Across racial/ethnic groups, the NYC Asian population, and the foreign-born Chinese in particular, had the highest concentrations of all three metals. Mercury levels were elevated 39% in the highest relative to the lowest income group (95% CI, 21–58%). Blood mercury concentrations in adults who reported consuming fish or shellfish 20 times or more in the last 30 days were 3.7 times the levels in those who reported no consumption (95% CI, 3.0–4.6); frequency of consumption explained some of the elevation in Asians and other subgroups.

Conclusions: Higher than national blood mercury exposure in NYC adults indicates a need to educate New Yorkers about how to choose fish and seafood to maximize health benefits while minimizing potential risks from exposure to mercury. Local biomonitoring can provide valuable information about environmental exposures.

Key words: biomonitoring, blood, cadmium, fish, lead, mercury, methylmercury, NYC HANES, seafood, survey. *Environ Health Perspect* 115:1435–1441 (2007). doi:10.1289/ehp.10056 available via http://dx.doi.org/ [Online 23 July 2007]

Lead, cadmium, and mercury are naturally occurring metals, but most human exposure occurs as a consequence of human activities. Mounting awareness and concern about environmental pollutants and their adverse health effects have led to an increase in measures to protect the public from avoidable exposures.

Blood lead concentrations in the United States have declined dramatically since the 1970s because of the phaseout of leaded gasoline, the ban of lead in paint and consumer products, and the discontinuation of lead use in plumbing and domestically manufactured soldered cans (Annest et al. 1983; Brody et al. 1994; Muntner et al. 2003; Pirkle et al. 1994). However, even at current lower levels, evidence suggests that pre- or postnatal exposure can potentially impair a child's intellectual function (Baghurst et al. 1992; Canfield et al. 2003; Gomaa et al. 2002; Lanphear et al. 2005; Schnaas et al. 2006). Low-to-moderate levels of lead exposure in pregnancy may also increase the risk of spontaneous abortion (Borja-Aburto et al. 1999) and preterm birth (Andrews et al. 1994). In the general adult population, lead exposure has been associated with elevated blood pressure and hypertension (Martin et al. 2006; Nash et al. 2003), kidney disease (Kim et al. 1996), peripheral arterial disease (Muntner et al. 2003; Navas-Acien et al. 2004), and cardiovascular and all-cause mortality (Menke et al. 2006; Schober et al. 2006).

Cadmium occurs naturally in some soils in addition to being deposited through emissions from mining operations and fossil fuel combustion, application of phosphate fertilizer or sewage sludge, and disposal of cadmium-containing products [Agency for Toxic Substances and Disease Registry (ATSDR) 1999]. Tobacco and food crops can take up cadmium from the soil, and shellfish can accumulate cadmium from the aquatic environment, making cigarette smoke and diet the principal sources of nonoccupational exposure in the United States. Epidemiologic evidence has linked relatively low-level cadmium exposure to renal dysfunction (Buchet et al. 1990; Jarup and Alfven 2004) and decreased bone mineral density (Åkesson et al. 2006; Staessen et al. 1999).

Exposure to mercury in the United States occurs predominantly from consumption of predatory fish that have bioaccumulated methylmercury from the aquatic environment (Bjornberg et al. 2003; Sanzo et al. 2001; Svensson et al. 1992). Methylmercury can cross the blood–brain barrier and interfere with functioning of the central nervous system. Children's developing nervous systems appear to be most vulnerable [National Research Council (NRC) 2000]. Deficits in language, attention, and memory among children exposed *in utero* have been reported in studies from the Faroe Islands, New Zealand, and the United States (Crump et al. 1998; Grandjean et al. 1999; Oken et al. 2005). Because methylmercury easily crosses the placenta (Ask et al. 2002; Vahter et al. 2000) and concentrates in fetal blood (Stern and Smith 2003), exposure in women of reproductive age is of particular concern. There is also evidence that methylmercury exposure in adulthood might interfere with vision, motor function, and memory (Lebel et al. 1998; Yokoo et al. 2003) as well as increase the risk of cardiovascular disease (Virtanen et al. 2007).

Ongoing surveillance of exposure to toxic substances is essential for identifying and targeting high-risk groups, evaluating interventions, tracking exposure over time, and monitoring exposures during emergency situations. New York State (NYS) law requires that all children be tested for lead at 1 and 2 years of age. NYS law also requires clinical laboratories to report all blood lead levels and elevated levels of mercury and cadmium in blood or urine to the State Heavy Metals Registry. However, testing among adults is voluntary and, therefore, likely to overrepresent higher-risk groups, for example, those in

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We thank M. Fiebach for managing data.

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certain occupations or who request tests because of known or suspected exposures.

In 2004 New York City (NYC) conducted the first-ever local health and nutrition examination survey [NYC Health and Nutrition Examination Survey (HANES)] in a representative sample of NYC adults. The survey measured blood concentrations of lead, mercury, and cadmium using a design that mirrored the National Health and Nutrition Examination Survey (NHANES). In the present article we describe blood metal concentrations by demographic and behavioral characteristics. Results will be used to prioritize public health actions in NYC, where demographics and environment differ in many respects from the United States as a whole.

Methods

Sample selection. The NYC HANES was a population-based, cross-sectional survey representing the civilian, noninstitutionalized adult population (20 years of age and older) residing in the five boroughs (counties) of NYC and was conducted between June and December 2004. Participants were recruited into the study using a three-stage cluster sampling design. The stages of sample selection were *a*) selection of census blocks, or groups of blocks; *b*) random selection of households within selected segments; and *c*) random selection of study participants within households. No oversampling of demographic groups was done.

Data collection. Selected subjects were invited to any of four clinic sites in the boroughs of Manhattan, Brooklyn, the Bronx, and Queens for interview and blood collection. Using a face-to-face, computer-assisted personal interview, study participants were asked their age, sex, race/ethnicity (White; Black/African American; Asian/Hawaiian/Pacific Islander, henceforth referred to as "Asian," as there are few Hawaiians and Pacific Islanders in NYC; Native American/Alaskan Native or other; and whether they consider themselves to be Hispanic/Latino), education, income, smoking status, place of birth, length of time in the United States, occupation, and consumption of fish or shellfish in the past 30 days. Current job information was categorized according to the Standard Occupational Classification System 2000 (U.S. Bureau of Labor Statistics 2000). The survey instrument was translated into Spanish; interviews in other languages were conducted using a staff or family member proxy or a telephone translation service. Blood specimens were collected by venipuncture using supplies provided specifically for trace metal measurements.

The NYC HANES protocol was approved by the NYC Department of Health and Mental Hygiene (NYC DOHMH) and the NYS Department of Health (NYS DOH) Institutional Review Boards. Study participants provided written, informed consent, and those who provided interview and laboratory data were remunerated $100 for their time. More information on data collection and protocols, as well as a detailed description of the study design, has been published (Thorpe et al. 2006).

Of the 4,026 households selected, 3,388 (84%) completed an eligibility interview. Of the 3,047 selected, eligible survey participants, 1,811 (59%) completed the interview and provided a blood sample, yielding an overall response rate of 50%.

Laboratory methods. Specimens were shipped to the Wadsworth Center's Trace Elements Laboratory at the NYS DOH, and stored at –80°C until analyzed. The Wadsworth Center's Laboratory is certified under the federal Clinical Laboratory Improvements Amendments of 1988 (CLIA-88 1992) and holds an NYS DOH clinical laboratory permit for blood lead and trace elements.

Total mercury, lead, and cadmium were determined in whole blood using a PerkinElmer Sciex (PerkinElmer, Shelton, CT) ELANDRC Plu inductively coupled plasma–mass spectrometer (ICP-MS). The ICP-MS method has been validated for biomonitoring measurements (Palmer et al. 2006), and performance is assessed periodically through participation in four external quality assessment schemes, as well as the NYS DOH's proficiency testing program for trace elements in whole blood. The ICP-MS instrument was calibrated for each of the metals using matrix-matched calibration standards. All calibration standards were traceable to the National Institute of Standards and Technology (NIST, Gaithersburg, MD).

Internal quality control (IQC) materials covering the range of exposure expected in the U.S. population were analyzed at the beginning and end of each batch of blood specimens and throughout each analytical run. The IQC samples were prepared in-house from whole blood obtained from lead-dosed animals and supplemented with inorganic cadmium, inorganic mercury, and methylmercury chloride. NIST Standard Reference Material 966 (Toxic Metals in Bovine Blood) was periodically analyzed throughout the study to maintain independent validation. Full details regarding the characterization of the IQC pools, including metal concentrations, and QC performance statistics have been described elsewhere (Palmer et al. 2006).

Method detection limits for lead, cadmium, and mercury were 0.05 µg/L, 0.09 µg/L, and 0.17 µg/L, respectively. Typical repeatability, or between-run imprecision, was 1.4–1.7% for lead, 3.1–4.1% for cadmium, and 2.6–3.7% for mercury. A repeat analysis was performed on any specimens exceeding the upper threshold of 4 µg/L for cadmium, 10 µg/dL for lead, or 10 µg/L for mercury. In addition 2.5% of all blood specimens were randomly selected for re-analysis.

Variable definition. Education was dichotomized by collapsing adjacent categories with similar geometric means. This resulted in collapsing categories whose geometric means differed by no more than 6%. For the lead analyses, participants were dichotomized into having up to a high school diploma and some college or higher. For the mercury and cadmium analyses, participants were dichotomized into having less than a bachelor's degree and a bachelor's degree or higher.

Smoking status was defined as current, former, or never smoker. Ever smoking was defined as having smoked at least 100 cigarettes in one's lifetime. Those who reported smoking 20 cigarettes or more per day (n = 83) were considered heavy smokers.

In addition to the broad race/ethnicity classifications of non-Hispanic White, non-Hispanic Black, non-Hispanic Asian, and Hispanic, we further classified as foreign-born Chinese any participant who was Asian and either reported a place of birth in China, Hong Kong, or Taiwan, or else requested a Chinese language interview (n = 93). The Chinese represent the largest subpopulation in the NYC Asian community.

We dichotomized blood metal concentrations using selected cut points. Mercury was dichotomized at ≥ 5 µg/L (the NYS reportable level) and ≥ 15 µg/L (the NYS investigation level). Lead was dichotomized at ≥ 5 µg/dL and ≥ 10 µg/dL, consistent with reporting in previous publications (Muntner et al. 2005; Schober et al. 2006).

Statistical analysis. We applied sample weights to adjust for differential selection probabilities and survey nonresponse. Weights were poststratified to reflect the age, sex, race/ethnicity, and borough of residence breakdown of the NYC population (U.S. Census Bureau 2000). Weights are applied to all estimates presented here. We used SUDAAN software, version 9 (Research Triangle Institute, Research Triangle Park, NC) to account for the complex sampling design. Relative standard errors (RSEs) were computed for estimated means and prevalence. Estimates with RSEs >30% were noted as statistically unstable (National Center for Health Statistics 2005)

We calculated crude population geometric means for blood metal concentrations by taking the antilog of the mean of the natural

log-transformed values. Upon visual inspection, logging the values made a substantial improvement toward the approximation of a normal distribution. We used the method of Korn and Graubard (1998) to estimate the 95th and 97.5th percentiles and their 95% confidence intervals (CIs) for blood metal concentrations. We provide the 95th percentile to allow direct comparison to NHANES estimates; we provide the 97.5th percentile because it is a clinical reference value used to interpret individual test results (National Committee for Clinical Laboratory Standards 2000).

We used *t*-tests to compare geometric mean and prevalence estimates across categories of nominal predictors. To test for trends across continuous predictors, we categorized income, education, years in the United States (among the foreign-born), and fish consumption variables into four ordinal levels (scored 1–4); we used age in continuous form. To test for trends across geometric means, we used the *p*-value associated with the beta coefficient from a crude linear regression of the natural logarithm of the metal concentration on the predictor. To test for a trend in prevalence, we used *p*-values associated with the beta coefficient from a crude binary linear model that regressed having an elevated metal (0 or 1) on the predictor (Fieldstein 1966). The binary linear model is equivalent to assuming that the prevalence (or proportion) increases linearly.

We fit multiple linear regressions of the log-metal concentrations on the predictor variables. We excluded persons categorized as "Native American or Non-Hispanic Other" race/ethnicity because of small numbers ($n = 27$), and those with missing covariate data ($n = 77$), in these models. To assess the relation between blood lead and cadmium, we added blood cadmium concentration to the adjusted model of lead concentration, and vice versa. The exponentiated model coefficients represent the proportional change in the arithmetic mean associated with each level of the predictor, relative to a referent level, adjusting for the other predictors in the model. We considered a result to be statistically significant if the 95% CI did not include one ($p < 0.05$).

Results

The geometric mean blood lead concentration in NYC adults was 1.79 µg/dL (95% CI, 1.73–1.86). Sample levels all exceeded the limit of detection, and ranged between 0.33 and 37.5 µg/dL. There were eight people with blood lead concentrations > 10 µg/dL (statistically unstable population prevalence = 0.5%), and two exceeded the NYS adult investigation level of 25 µg/dL. Most of these eight were male (7) and born outside the United States (7). An estimated 4.8% of the NYC adult population had lead levels ≥ 5 µg/dL (95% CI, 3.7%–6.1%), including 12 women of reproductive age (20–49 years of age) (statistically unstable population prevalence = 1.4%). The 97.5th percentile for blood lead concentration overall was 6.29 µg/dL.

We describe blood lead results in Table 1. Geometric mean blood lead concentrations increased with age and decreased with income, education, and length of residence in the United States for the foreign-born (*p*-values for trend tests < 0.04). Blood lead concentrations were highest in heavy smokers (2.49 µg/dL), the foreign-born Chinese (2.66 µg/dL), and those working in construction and maintenance (2.86 µg/dL). Upon removal of the latter group, the geometric mean blood lead level in smokers decreased slightly to 2.00 µg/dL (95th percentile = 5.51 µg/dL), suggesting some confounding of the smoking association by occupation. Prevalence of current smoking among construction and maintenance workers was 45% compared with a citywide estimate of 23%.

The patterns of lead concentrations across population subgroups were similar

Table 1. Blood lead concentrations, geometric means, adjusted proportional change in means, 95th percentiles, and prevalence (≥ 5 µg/dL) in NYC adults by population subgroups.

Variable	No.[a]	Crude weighted geometric mean blood lead [µg/dL (95% CI)]	Adjusted proportional change in mean blood lead [µg/dL (95% CI)][b]	Crude weighted 95th percentile blood lead [µg/dL (95% CI)]	No. with blood lead ≥ 5 µg/dL	Crude weighted % blood lead ≥ 5 µg/dL (95% CI)
Total	1,811	1.79 (1.73–1.86)	—	4.81 (4.37–5.51)	78	4.8 (3.7–6.1)
Sex						
Male	762	2.14 (2.03–2.25)	1.36 (1.28–1.44)	5.87 (5.01–6.60)	53	7.4 (5.4–10.1)
Female	1,049	1.54 (1.48–1.62)	1.00 (reference)	3.88 (3.65–4.36)	25	2.5 (1.6–3.9)
Age (years)						
20–39	903	1.42 (1.35–1.49)	1.00 (reference)	3.71 (3.23–4.24)	19	1.8 (1.1 –2.8)
40–59	673	1.99 (1.89–2.10)	1.38 (1.31–1.47)	5.56 (4.31–6.29)	38	5.7 (4.0–7.9)
≥ 60	235	2.40 (2.23–2.58)	1.70 (1.54–1.87)	5.77 (4.58–6.95)	21	9.1 (5.7–14.2)
Race/ethnicity[c]						
White, non-Hispanic	529	1.89 (1.77–2.01)	1.15 (1.05–1.26)	4.38 (4.23–5.26)	16	4.0 (2.3–6.8)
Black, non-Hispanic	390	1.73 (1.63–1.84)	1.08 (1.00–1.17)	5.56 (4.08–6.51)	22	6.5 (4.2–10.0)
Asian, non-Hispanic	231	2.14 (1.95–2.35)	1.31 (1.17–1.48)	5.51 (4.61–6.09)	16	7.3 (4.7–11.5)
Hispanic	630	1.62 (1.53–1.72)	1.00 (reference)	4.29 (3.78–5.02)	24	3.6 (2.2–5.8)
Place of birth						
U.S.	882	1.70 (1.62 -1.80)	1.00 (reference)	4.46 (4.20–5.56)	31	4.6 (3.1–6.8)
Outside U.S.	923	1.90 (1.81 -1.99)	1.14 (1.06–1.23)	4.97 (4.39–5.78)	47	5.0 (3.7–6.7)
Family income ($US)						
< 20,000	610	1.90 (1.79–2.01)	1.00 (reference)	5.32 (4.68–5.87)	39	6.5 (4.6–9.2)
20,000–49,999	566	1.76 (1.66–1.87)	0.96 (0.89–1.03)	5.01 (3.92–6.51)	22	5.4 (3.2–8.9)
50,000–74,999	256	1.70 (1.57–1.84)	0.96 (0.88–1.04)	4.24 (3.42–6.29)	15	3.0 (1.8, 5.0)
≥ 75,000	304	1.72 (1.60–1.85)	0.97 (0.89–1.06)	4.19 (3.69–4.65)		
Education						
High school diploma or less	862	1.95 (1.86–2.05)	1.09 (1.02–1.17)	5.76 (4.67–6.24)	52	6.8 (5.0–9.2)
Some college or more	941	1.68 (1.60–1.76)	1.00 (reference)	4.31 (3.89–4.73)	26	3.1 (2.0–4.8)
Smoking status						
Never smoked	1,036	1.61 (1.54–1.68)	1.00 (reference)	4.35 (3.79–5.30)	36	3.7 (2.5–5.5)
Former smoker	310	2.01 (1.88–2.16)	1.08 (0.99–1.17)	4.68 (4.03–6.72)	12	4.8 (2.5–9.0)[d]
Current smoker	449	2.09 (1.96–2.23)	1.31 (1.22–1.41)	6.00 (4.83–6.81)	30	7.3 (5.0–10.6)

[a]Totals do not all equal 1,811 because of missing data. [b]The exponentiated β coefficient from a log-linear multiple regression that includes all covariates in the table. Sample size for adjusted analysis is 1,707, after excluding study participants for whom covariate data are missing. [c]Excludes 27 participants who self-classified as "other." [d]Statistically unstable population estimate.

after we adjusted for predictors simultaneously in a log-linear regression—with several exceptions. The crude association between decreasing income and increasing geometric mean blood lead was no longer apparent (p-value for trend test = 0.54), and former smokers had only 8% higher blood lead concentrations than never smokers (compared with a crude elevation of 26%). Age remained the strongest predictor of blood lead. Upon adding blood cadmium to the adjusted model, a 1-μg/L increase predicted a 22% elevation (95% CI, 17–28%) in mean blood lead concentration.

The geometric mean blood cadmium concentration in NYC adults was 0.77 μg/L (95% CI, 0.75–0.80) as shown in Table 2. All sample levels exceeded the limit of detection and ranged from 0.25 to 9.67 μg/L. There were four blood cadmium levels > 5 μg/L, two of which were measured in foreign-born Chinese males who also had blood concentrations of mercury > 15 μg/L (n = 1) or lead > 10 μg/dL (n = 1). No samples attained the NYS reportable level for cadmium of 10 μg/L, although the highest measured level of 9.67 μg/L came close. The 97.5th percentile for blood cadmium concentration overall was 2.49 μg/L.

Blood cadmium levels were most strongly associated with smoking status. Heavy smokers had the highest geometric mean cadmium concentration (1.58 μg/L) of all subgroups examined. However, the geometric mean among foreign-born Chinese New Yorkers (1.34 μg/L) exceeded that of current smokers (1.22 μg/L), even though the estimated prevalence of smoking in this population subgroup (21%) was not higher than that of the general adult population (24%).

Results from a multiple linear regression were consistent with the patterns of crude geometric means observed across population subgroups. Current smoking and Asian race/ethnicity remained the strongest predictors of elevated blood cadmium. Blood lead was a relatively strong predictor of blood cadmium. After adjusting for other predictors, a 5-μg/dL increase in blood lead concentration predicted a 17% elevation in blood cadmium concentration (95% CI, 5%–31%).

The geometric mean blood mercury concentration among NYC adults was 2.73 μg/L (95% CI, 2.58–2.89) as shown in Table 3. All sample values exceeded the limit of detection and ranged between 0.21 and 35.78 μg/L. About one quarter (24.8%; 95% CI, 22.2–27.7%), or 1.4 million NYC adults, had blood mercury concentrations equaling or exceeding the NYS reportable level of 5 μg/L. There were 54 participants (population prevalence = 2.8%) who exceeded the NYS investigation level of 15 μg/L. Women 20–49 years of age had a geometric mean blood mercury level of 2.64 μg/L and a 23.8% prevalence of blood mercury ≥ 5 μg/L, similar to the total population. The 97.5th percentile for blood mercury concentration overall was 15.37 μg/L

Frequent consumption of fish or shellfish was associated with increasing mercury levels (p-values for trend test < 0.01 for geometric mean and prevalence ≥ 5 μg/L) (Table 3). The geometric mean blood level in those who reported consuming fish or shellfish 20 times or more in the last 30 days (5.65 μg/L) was more than 4 times the level of those who did not consume fish or shellfish (1.31 μg/L). Over half (56.2%) of those who reported consuming fish 20 or more times in the last 30 days had mercury levels ≥ 5 μg/L, almost eight times the prevalence in those who did not consume fish or shellfish (7.3%).

People born outside the United States had higher mercury levels than those born in the United States; however we did not see a trend toward increasing mercury concentration with shorter time in the United States as we did with lead levels. In contrast, those who had lived in the United States for > 10 years had a higher crude geometric mean blood mercury level than newer arrivals (p < 0.01).

The geometric mean blood mercury level in Asians was higher than other racial/ethnic groups (4.11 μg/L). The 95th percentile was among the highest (19.19 μg/L). The geometric mean in foreign-born Chinese New Yorkers was even higher (7.26 μg/L), surpassing that of all other subgroups we examined. Almost half of adult Asian New Yorkers (46.2%) had blood mercury ≥ 5 g/L. Among the 93 foreign-born Chinese New Yorkers in the survey, 68 had blood mercury concentrations ≥ 5 μg/L (population prevalence = 71.7%), and 19 of these were ≥ 15 μg/L (population prevalence= 20.0%).

Fish consumption was the strongest predictor of increasing blood mercury concentration in a multiple linear regression of log-mercury concentration on the predictors in Table 3. The increased blood mercury levels in Asians relative to Hispanics (referent group) dropped from a proportional increase of 1.86–1.29 after adjustment, whereas the association with higher income was attenuated less (down to 1.39 from 1.49). The crude geometric mean blood mercury remained lower in current smokers compared with never smokers (p < 0.01) and those with less education (p-value for trend test < 0.01), but the associations were attenuated and no longer statistically significant in the adjusted model.

Table 2. Blood cadmium concentrations, geometric means, adjusted proportional change in means, and 95th percentiles in NYC adults by population subgroups.

Variable	No.[a]	Crude weighted geometric mean blood cadmium [μg/L (95% CI)]	Adjusted proportional change in mean blood cadmium [μg/L (95% CI)][b]	Crude weighted 95th percentile blood cadmium [μg/L (95% CI)]
Total	1,811	0.77 (0.75–0.80)	—	1.88 (1.73–2.07)
Sex				
Male	762	0.76 (0.73–0.79)	1.00 (reference)	1.95 (1.57–2.32)
Female	1,049	0.79 (0.76–0.82)	1.07 (1.03–1.11)	1.83 (1.73–2.01)
Age (years)				
20 to 39	903	0.72 (0.69–0.75)	1.00 (reference)	1.82 (1.58–2.06)
40 to 59	673	0.84 (0.80–0.89)	1.16 (1.11–1.22)	2.19 (1.90–2.52)
≥ 60	235	0.77 (0.73–0.81)	1.15 (1.08–1.23)	1.52 (1.32–1.63)
Race/ethnicity[c]				
White, non-Hispanic	529	0.73 (0.69–0.77)	1.04 (0.98–1.10)	1.71 (1.44–2.01)
Black, non-Hispanic	390	0.80 (0.75–0.86)	1.11 (1.04–1.18)	1.97 (1.74–2.48)
Asian, non-Hispanic	231	0.99 (0.90–1.09)	1.41 (1.27–1.57)	2.36 (1.65–3.43)
Hispanic	630	0.73 (0.71–0.76)	1.00 (reference)	1.73 (1.58–1.79)
Place of birth				
U.S.	882	0.76 (0.73–0.80)	1.00 (reference)	1.95 (1.75–2.32)
Outside U.S.	923	0.79 (0.75–0.82)	1.02 (0.98–1.07)	1.73 (1.52–2.19)
Family income ($US)				
< 20,000	610	0.86 (0.81–0.90)	1.00 (reference)	2.33 (1.90–2.75)
20,000–49,999	566	0.77 (0.73–0.80)	0.94 (0.89–0.99)	1.76 (1.49–2.22)
50,000–74,999	256	0.74 (0.69–0.79)	0.92 (0.86–0.99)	1.76 (1.51–2.71)
≥ 75,000	304	0.69 (0.65–0.74)	0.91 (0.85–0.97)	1.43 (1.17–1.71)
Education				
Less than bachelor's	1,252	0.82 (0.79,0.85)	1.09 (1.04,1.15)	2.02 (1.87-2.4)
Bachelor's or greater	551	0.69 (0.66,0.72)	1.00 (reference)	1.43 (1.28-1.57)
Smoking status				
Never smoked	1,036	0.66 (0.64–0.68)	1.00 (reference)	1.28 (1.20–1.34)
Former smoker	310	0.71 (0.67–0.74)	1.07 (1.02–1.12)	1.32 (1.10–1.58)
Current smoker	449	1.22 (1.15–1.29)	1.88 (1.78–1.99)	3.00 (2.65–3.49)

[a]Totals do not all equal 1,811 because of missing data. [b]The exponentiated β coefficient from a log-linear multiple regression that includes all covariates in the table. Sample size for adjusted analysis is 1,707, after excluding study participants for whom covariate data are missing. [c]Excludes 27 participants who self-classified as "other."

Discussion

Findings presented here from the nation's first local HANES, conducted in NYC in 2004, suggest that there is variability in exposure to toxic metals across population subgroups. Blood lead increased most with age; blood cadmium increased most with cigarette smoking; and blood mercury was most strongly related to fish or shellfish consumption. New Yorkers who self-identified as Asian had the highest blood concentrations of all three metals compared with other racial/ethnic groups. Foreign-born Chinese New Yorkers, in particular, had higher mercury levels than the most frequent fish consumers, higher lead levels than the oldest New Yorkers, and higher cadmium levels than current smokers. The wide range of exposure to metals in a geographically contiguous but diverse urban population highlights the importance of local-level examination surveys in guiding public health actions.

NHANES 1999–2002 (CDC 2005a) provided national estimates of blood mercury concentration for women 16–49 years of age. The geometric mean blood mercury concentration in our slightly older sample of NYC women 20–49 years of age (2.64 µg/L) is more than 3 times the NHANES 2001–2002 estimate (0.83 µg/L) [Centers for Disease Control (CDC) 2005a; Figure 1]. This elevation is consistent with a previous report of higher blood mercury levels in the Eastern coastal region of the United States relative to the United States as a whole (Mahaffey 2005).

Blood mercury levels were higher in NYC than nationally across similar levels of reported fish or shellfish consumption (Mahaffey et al. 2004). A possible explanation for this observation is that New Yorkers consume more heavily contaminated fish. A similar scenario may be occurring in the higher income groups, where mercury levels remain elevated even after adjustment for frequency of fish or shellfish consumption. Elevations in economically advantaged individuals may be due to consumption of more expensive fish, such as swordfish, which tend to be higher in mercury (Hightower and Moore 2003). However, even comparing people who reported no fish or shellfish consumption in the past 30 days, the geometric mean blood mercury concentration among New Yorkers was 3 times the national level (Mahaffey et al. 2004).

Blood metal concentrations among Asians have not routinely been reported from the NHANES because of sample size limitations. However, an analysis of 1999–2002 data identified the aggregate of Asians, Pacific Islanders, Native Americans and multiracial groups as having the highest

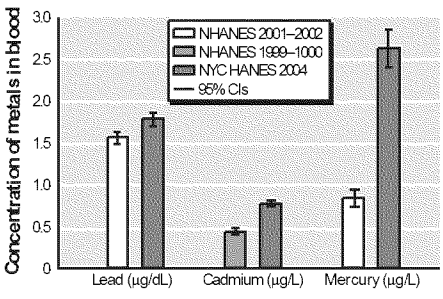

Figure 1. Geometric mean and 95% CI for blood lead, cadmium and mercury concentrations in adults residing in NYC compared with the United States overall, NYC HANES 2004, and NHANES 1999–2002 (CDC 2005a).[a]

[a]Blood mercury comparison for women age 16–49 years (NHANES) and 20–49 years (NYC HANES).

Table 3. Blood mercury concentrations, geometric means, adjusted proportional change in means, 95th percentiles, and prevalence (≥ 5 µg/L) in NYC adults by population subgroups.

Variable	No.[a]	Crude weighted geometric mean blood mercury [µg/dL (95% CI)]	Adjusted proportional change in mean blood mercury [µg/dL (95% CI)][b]	Crude weighted 95th percentile blood mercury [µg/dL (95% CI)]	No. with blood mercury ≥ 5 µg/dL	Crude weighted % blood mercury ≥ 5 µg/dL (95% CI)
Total	1,811	2.73 (2.58–2.89)	—	11.03 (9.72–13.08)	431	24.8 (22.2–27.7)
Sex						
Male	762	2.67 (2.48–2.87)	0.95 (0.88–1.03)	10.70 (8.82–12.75)	195	25.5 (22.2–29.1)
Female	1,049	2.78 (2.61–2.97)	1.00 (reference)	11.31 (9.63–14.21)	236	24.3 (21.0–27.9)
Age (years)						
20–39	903	2.38 (2.20–2.56)	1.00 (reference)	9.54 (7.89–10.92)	179	21.5 (18.2–25.2)
40–59	673	3.23 (2.97–3.51)	1.30 (1.19–1.41)	15.31 (11.70–19.07)	198	30.3 (26.2–34.8)
≥ 60	235	2.71 (2.46–2.98)	1.22 (1.09–1.38)	8.07 (6.78–9.93)	54	22.3 (17.0–28.6)
Race/ethnicity[c]						
White, non-Hispanic	529	2.83 (2.62–3.07)	1.07 (0.96–1.20)	10.85 (9.36–14.21)	136	25.5 (21.5–29.9)
Black, non-Hispanic	390	2.61 (2.36–2.88)	1.05 (0.94–1.16)	9.26 (7.77–12.26)	81	23.3 (18.6–28.9)
Asian, non-Hispanic	231	4.11 (3.24–5.21)	1.29 (1.03–1.61)	19.19 (14.03–23.95)	112	46.2 (36.6–56.1)
Hispanic	630	2.27 (2.11–2.43)	1.00 (reference)	8.46 (7.03–9.93)	96	16.7 (13.5–20.5)
Place of birth						
U.S.	882	2.39 (2.24–2.56)	1.00 (reference)	8.32 (7.59–10.72)	152	18.9 (15.9–22.4)
Outside U.S.	923	3.15 (2.89–3.42)	1.38 (1.24–1.53)	13.39 (10.80–17.00)	279	31.3 (27.2–35.9)
Family income ($US)						
< 20,000	610	2.39 (2.17–2.63)	1.00 (reference)	9.84 (7.96–14.39)	113	19.3 (15.1–24.3)
20,000–49,999	566	2.55 (2.36–2.76)	1.05 (0.96–1.15)	9.89 (7.69–11.20)	116	20.5 (17.0–24.4)
50,000–74,999	256	3.02 (2.70–3.38)	1.21 (1.06–1.39)	11.19 (8.14–15.37)	75	30.4 (25.0–36.4)
≥ 75,000	304	3.56 (3.21–3.95)	1.39 (1.21–1.58)	14.69 (11.13–17.73)	111	37.2 (31.4–43.3)
Education						
Less than bachelor's	1,252	2.54 (2.37–2.72)	1.00 (reference)	10.56 (8.50–13.39)	262	21.7 (18.6–25.1)
Bachelor's or greater	551	3.16 (2.95–3.39)	1.07 (0.98–1.18)	11.54 (9.63–14.54)	169	31.5 (27.5–35.7)
Smoking status						
Never smoked	1,036	2.82 (2.65–3.01)	1.00 (reference)	10.72 (9.34–12.27)	257	26.6 (23.5–30.1)
Former smoker	310	2.83 (2.51–3.19)	0.96 (0.86–1.08)	11.76 (9.13–15.37)	86	25.6 (20.3–31.8)
Current smoker	449	2.43 (2.21–2.68)	0.93 (0.84–1.03)	11.34 (8.02–14.87)	84	19.8 (16.0–24.2)
Fish or shellfish consumption (last 30 days)						
Never	209	1.31 (1.14–1.50)	1.00 (reference)	5.39 (4.40–7.16)	14	7.3 (4.0–13.0)
Up to 9 times	1,216	2.60 (2.46–2.74)	1.90 (1.64–2.21)	9.34 (7.96–10.27)	237	20.5 (17.8–23.4)
10–19 times	255	4.25 (3.79–4.76)	2.87 (2.38–3.46)	19.19 (12.03–23.45)	111	44.1 (37.0–51.4)
20 times or more	114	5.65 (4.80–6.65)	3.70 (3.00–4.55)	18.31 (14.70–21.65)	65	56.2 (45.4–66.5)

[a]Totals do not all equal 1,811 because of missing data. [b]The exponentiated β coefficient from a log-linear multiple regression that includes all covariates in the table. Sample size for adjusted analysis is 1,707, after excluding study participants for whom covariate data are missing. [c]Excludes 27 participants who self-classified as "other."

mercury levels of all race/ethnicities (Hightower et al. 2006), similar to our findings. In NYC, fish consumption is the most likely explanation for the racial and ethnic differences in mercury exposure; consumption of at least 20 meals of fish or seafood in the last 30 days was highest in Asians (19%) compared with Whites or Blacks (5.5% each) and Hispanics (1.3%).

We are not aware of NHANES reports that describe elevated blood cadmium or lead in Asians, either alone or as an aggregate group, so we do not know whether the higher levels we measured among Asian New Yorkers mirror national data. Current smoking did not explain the higher cadmium or lead levels in Asians; in fact, prevalence of current smoking was slightly lower among Asian New Yorkers compared with the citywide estimate. Shellfish consumption is a possible source of the higher cadmium levels observed in Asians. Exposure could have occurred outside the United States as well, as cadmium and lead can remain in the body for decades, and body stores may serve as a source of subsequently measured metals in blood (Gulson et al. 1995; Nordberg and Kjellstrom 1979; Smith et al. 1996). In NYC, a large percentage (92%) of Asian adults are foreign-born (U.S. Census Bureau 2000).

The geometric mean blood lead concentration in NYC adults (1.79 µg/dL) is similar to the 2001–2002 national estimate (1.56 µg/dL; CDC 2005a; Figure 1). Despite declining trends (Muntner et al. 2005), current exposure levels have been associated with adverse health effects in children and adults (Canfield et al. 2003; Menke et al. 2006). In adults, nonoccupational lead exposure can occur during renovation of homes or other structures that used lead-based paints in the past. Residential remodeling was the likely source of exposure for the largest number of nonoccupational cases of blood lead ≥ 25 µg/dL reported to the NYS Heavy Metals Registry 2000–2005 (New York State Department of Health 2006). Other exposure sources included target shooting, ingestion (pica), lead-glazed pottery, soil, dust, and some imported food, spices and traditional medicines (ATSDR 2005; CDC 2005b; Saper et al. 2004). Cigarette smoke contains only small amounts of lead (ATSDR 2005), but our results are consistent with previous reports of positive associations between passive and active smoking and blood lead (Mannino et al. 2005; Shaper et al. 1982). It is possible that the association we observed was confounded by occupational lead exposure, as lead levels among current smokers decrease upon exclusion of persons who reported working in construction or maintenance.

The geometric mean blood cadmium concentration in NYC adults (0.77 µg/L) is slightly higher than the 1999–2000 national estimate for adults (0.47 µg/L; CDC 2005a; Figure 1). Though the difference appears to be statistically significant (judging from the nonoverlapping confidence intervals), the clinical or biological significance of a 0.3 µg/L elevation is not known. Decreased bone mineral density in older women has been associated with blood cadmium levels ≥ 1.1 µg/L (Alfven et al. 2000), which are typical of current smokers and the foreign-born Chinese in our survey. Cadmium is a constituent of cigarette smoke (ATSDR 1999), and the strong association between current smoking and blood cadmium provides further motivation to prevent smoking initiation and to promote smoking cessation.

Our findings have some limitations. Although the sample selection was designed to be representative of the NYC adult population, we cannot rule out the presence of bias, as the overall response rate was 50%. However, to correct for bias, sample weights incorporated information on age, sex, race/ethnicity, income, education, language spoken at home, and household size, obtained either directly from interview or from neighborhood census data. We also note that the NHANES interview and examination response rate for a similarly aged population in the NYC area in 2004 was only slightly higher, 58% (personal communication with the NHANES program), compared with the 55% response in the NYC HANES (response rates for blood collection component of the examination are slightly lower in both surveys).

Self-reported exposure data are limited by respondents' memories and ability to answer questions. We do not know how accurately respondents were able to provide the number of times they ate fish or shellfish in the last 30 days. Furthermore, our questionnaire did not distinguish consumption of fish species according to mercury content. Consequently, confounding by contaminated fish and seafood consumption is likely to remain in our comparisons of mercury levels across population subgroups after adjustment for fish or shellfish consumption.

Laboratory methods for determining chemical exposures have become increasingly sensitive, so the detection of lead, mercury or cadmium in the blood of an adult does not necessarily imply a health risk. Findings are difficult to interpret in terms of public health impact, as reference doses are not necessarily meaningful threshold values for toxicity. The data we present attempt to describe exposures in the NYC adult population for the purpose of targeting intervention to high-risk groups and establishing baseline exposure levels.

A local HANES is an important source of information about the health of a community, particularly in the area of environmental exposures that are difficult—if not impossible—to assess without laboratory data, and that may vary across the nation. Our findings suggest that while NYC is keeping pace with national reductions in exposure to lead, exposure to mercury is elevated relative to national levels. The most significant source of exposure to mercury is likely to be fish consumption, implying a need to educate New Yorkers about how to choose fish to maximize health benefits while minimizing health risks. Asians may be at increased risk of exposure to mercury and other metals. Because lead and mercury are known to harm the developing nervous system and because both metals cross the placenta, it is critical that we support efforts to track and develop methods of intervention to reduce exposures in women of reproductive age. Our findings are also a reminder of the ramifications of failing to control mercury emissions into the environment.

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Adult Women's Blood Mercury Concentrations Vary Regionally in the United States: Association with Patterns of Fish Consumption (NHANES 1999–2004)

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Background: The current, continuous National Health and Nutrition Examination Survey (NHANES) has included blood mercury (BHg) and fish/shellfish consumption since it began in 1999. NHANES 1999–2004 data form the basis for these analyses.

Objectives: This study was designed to determine BHg distributions within U.S. Census regions and within coastal and noncoastal areas among women of childbearing age, their association with patterns of fish consumption, and changes from 1999 through 2004.

Methods: We performed univariate and bivariate analyses to determine the distribution of BHg and fish consumption in the population and to investigate differences by geography, race/ethnicity, and income. We used multivariate analysis (regression) to determine the strongest predictors of BHg among geography, demographic factors, and fish consumption.

Results: Elevated BHg occurred more commonly among women of childbearing age living in coastal areas of the United States (approximately one in six women). Regionally, exposures differ across the United States: Northeast > South and West > Midwest. Asian women and women with higher income ate more fish and had higher BHg. Time-trend analyses identified reduced BHg and reduced intake of Hg in the upper percentiles without an overall reduction of fish consumption.

Conclusions: BHg is associated with income, ethnicity, residence (census region and coastal proximity). From 1999 through 2004, BHg decreased without a concomitant decrease in fish consumption. Data are consistent with a shift over this time period in fish species in women's diets.

Key words: blood, coastal, fish, mercury, NHANES, regional. *Environ Health Perspect* **117:000–000 (2009). doi:10.1289/ehp.11674 available via *http://dx.doi.org/* [Online 25 August 2008]**

Risk of mercury-associated adverse health effects (e.g., neuropsychological deficits) in children after *in utero* methylmercury (MeHg) exposures increases as Hg exposure rises [Mergler et al. 2007; National Research Council (NRC) 2000]. Blood Hg (BHg) and hair Hg concentrations are indicators of the magnitude of MeHg exposure. National estimates for the United States are based on data from the National Health and Nutrition Examination Survey (NHANES) (Mahaffey et al. 2004; McDowell et al. 2005). Mercury concentrations in blood obtained from women of childbearing age who participated in NHANES have been collected by the National Center for Health Statistics (NCHS) on a continuing basis since 1999. Hair Hg concentrations were determined only in the years 1999 and 2000 (McDowell et al. 2005).

Although the national estimates provide an overview for the United States, indications of regional differences within the United States are suggested from local data (Bellanger et al. 2000; Karouna-Renier et al. 2008; Knobeloch et al. 2005; McKelvey et al. 2007; Ortiz-Roque and López-Rivera 2004; Sato et al. 2006; Sechena et al. 2003; Stern et al. 2001). Women residing in New York City (McKelvey et al. 2007), Hawaii (Sato et al. 2006), and Florida (Karouna-Renier et al. 2008) had both higher fish consumption and higher Hg exposure than the national estimates from NHANES (Mahaffey et al. 2004). These U.S. data, as well as international data especially from island communities (Dewailly and Pereg 2004; Hsu et al. 2007; Sakamoto et al. 2007; Soong et al. 1991; see also Bermuda Biological Stations for Research 2004) suggested the importance of regional differences and proximity to coastal areas as predictors of increased MeHg exposure. In the present article, we used the NHANES data to identify differences in distribution of BHg across the four major U.S. Census regions (Northeast, Midwest, South, and West) and between coastal and noncoastal areas of the United States.

Selecting a BHg concentration to use as an index of excessive Hg exposure depends on dose–response analysis. Over the past decade, risk assessments describing association between human exposures to MeHg and occurrence of neurologic deficits have been developed by multiple countries and organizations [Agency for Toxic Substances and Disease Research 1999; Joint Food and Agriculture Organization/World Health Organization 2003; NRC 2000; U.S. Environmental Protection Agency (EPA) 2001; European Union 2002]. We discuss these risk assessments in more detail in the Supplemental Material [see especially Table 1 (http://www.ehponline.org/members/2008/11674/suppl.pdf)].

The current reference dose (RfD) used by the U.S. EPA was based on cord blood measurements and is associated with fetal BHg concentrations of 5.8 µg/L (NRC 2000; U.S. EPA 2001). However, differences have been found between maternal and cord blood concentrations due to bioconcentration of MeHg across the placenta (Butler Walker et al. 2004; Mahaffey et al. 2004; Mergler et al. 2007; Morrissette et al. 2004; NRC 2006; Stern and Smith 2003). As a result, maternal BHg concentrations as low as approximately 3.5 µg/L may be a concern. Therefore, we refer to BHg concentrations exceeding 3.5 and 5.8 µg/L as levels of concern for the purposes of this article.

Previous analyses of NHANES BHg data (Mahaffey et al. 2004) confirmed fish and shellfish consumption as the major source of blood organic Hg for the U.S. population. In the lower portion of the range of BHg concentrations currently considered relevant to the prevention of fetal neurotoxicity (i.e., ~ 3.5 to 5.8 µ g/L), organic Hg (i.e., MeHg) accounted for approximately 90% of total BHg for the general population not exposed occupationally to Hg (Mahaffey et al. 2004).

NHANES data have been used to describe the distribution of BHg concentrations in a nationally representative sample for adult women (Mahaffey et al. 2004) but have not previously been used to characterize regional and coastal exposure patterns. Analyses of NHANES data can be used to characterize major U.S. Census regions (Northeast, South, Midwest, and West) and estimate population distributions in these broad regions. Unbiased population estimates cannot be made for other U.S. geographic subdivisions, such as coastal and noncoastal

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regions, because weights have not been developed for them; however, distributional estimates can be made.

Explaining patterns of MeHg exposure is challenging because MeHg concentrations within and among fish species are known to vary by more than 10-fold (Mahaffey 2004; NRC 2006). Regional distributions of BHg and Hg exposure estimated from the patterns of fish consumption (i.e., Northeast, Midwest, South, and West , as well as overall coastal–noncoastal differences) remain questions.

The purposes of the present study of Hg exposures are to provide for the first time separate estimates of BHg distribution and fish consumption for the individual U.S. Census regions and for coastal and noncoastal populations. Such data are useful in determining where to focus efforts to reduce Hg exposure. The present analysis can be used to determine *a*) distributions of BHg concentrations and fish consumption that differ across the four U.S. Census regions and between the coastal and noncoastal populations, *b*) significant temporal trends in BHg levels and fish consumption between 1999 through 2004, and *c*) BHg concentrations associated with racial/ethnic and income level. Trends in patterns of fish consumption, if present, could be used to assess the impact of national fish advisories and Hg reduction programs. Data on geographic/ethnic groups and socioeconomic associations could be used to target intervention programs. The regional results can be generalized to provide population estimates for the U.S. Census regions.

Materials and Methods

Methodology for data analysis. We evaluated data for examinees who participated in NHANES during survey years 1999–2004 to assess the statistical association between seafood consumption and BHg by region of residence, race/ethnicity, and annual income. Further, we examined time trends for both BHg and fish consumption. NHANES is an annual survey conducted by the NCHS. The data include BHg levels, 24-hr dietary recall, and 30-day finfish and shellfish consumption frequency for women 16–49 years of age who reside in the United States. The NHANES sampling frame includes all 50 states. The documentation and publicly available data for NHANES can be found online [Centers for Disease Control and Prevention (CDC) 2006b]. The regional data are not publicly available but can be accessed by special request to the National Center for Health Statistics (NCHS) through its Research Data Center. Procedures for submitting a proposal in order to access data that are not publicly available can be found online (CDC 2006c). We performed all analyses using SAS, version 9.1 (SAS Institute Inc., Cary, NC).

Following NHANES analytic guidelines (CDC 2006a), we used SAS procedures that accurately incorporate the stratification and multistage sampling of NHANES: Proc SurveyMeans, Proc SurveyReg, and Proc SurveyFreq (SAS Institute Inc.). The weights provided by NCHS compensate for the oversampling of various subpopulations and adjust for nonresponse bias. We used weights for estimating statistics for coastal and noncoastal regions to retain these adjustments. Because we considered the variables of interest (BHg and fish consumption) to be related to some of the factors that were oversampled, we retained these adjustments to minimize the bias in the estimates. For example, NHANES oversampled Mexican Americans, who also have lower BHg than do other racial/ethnic groups. If the weights were not used to estimate the distribution of BHg, the results would be biased low. We recognize that some bias may remain within the estimates because the weights were not specifically created for the geographic regions of coastal and noncoastal; however, these subdivisions (e.g., coastal, noncoastal, Pacific, Atlantic) are based on counties, the primary sampling units of NHANES (CDC 2006a). All multivariate analyses were done unweighted because we included factors associated with the dependent variables and for which oversampling was based were included as covariates and thus adjusted for them in the modeling.

In order to estimate long-term Hg intake, we combined data collected through the 24-hr dietary recall and the 30-day fish frequency questionnaire to estimate 30-day Hg intake [for specific methodologies, see Mahaffey and Rice (1997); Mahaffey et al. (2004)]. If we found statistically significant differences in amount of fish consumed per meal from the 24-hr dietary recall by either coastal status (participants who lived in a county that bordered the Pacific or Atlantic Oceans, the Gulf of Mexico, or the Great Lakes vs. those who did not) or data release (1999–2000, 2001–2002, or 2003–2004), we calculated separate averages. We generated statistically representative estimates from these data using the statistical weights provided by NCHS and following the relevant analytical guidelines published by NCHS (CDC 2006a).

Methodology for defining coastal and noncoastal areas. Fish consumption is generally believed to be a major contributor to BHg concentration. We hypothesized that patterns of fish and shellfish consumption would vary between U.S. residents who live on or near the coast (within~ 25–50 miles) and those who live inland. We further hypothesized that fish consumption patterns, and thus BHg concentrations, may also vary by specific coast (e.g., residents near the Atlantic Coast may have different BHg concentrations than those on the coast of the Gulf of Mexico) and specific inland region (e.g., West vs. Midwest). To test these hypotheses, we categorized NHANES respondents as living in either a coastal or a noncoastal county and further categorized them by eight regions: Atlantic Coast, Northeast, Great Lakes, Midwest, South, Gulf of Mexico, West, and Pacific Coast.

The geographic unit used by NHANES is a county or county equivalent (CDC 2006a);

Table 1. Percentages of examinees and population estimates (in millions) of women with BHg concentrations ≥ 3.5 µg/L and ≥ 5.8 µg/L, by U.S. Census region and coastal status.

	U.S. Census region					Coastal status[a]	
BHg	Nation	Northeast	South	Midwest	West	Coastal	Noncoastal
Percent ≥ 3.5 µg/L (SE)	10.4 (1.0)	19.3 (4.1)	10.8 (1.0)	2.8 (0.9)	10.3 (1.3)	16.3 (1.8)	6.0 (1.0)
No. of women ≥ 3.5 µg/L (millions)	6.92	2.15	2.85	0.41	1.51		
Percent ≥ 5.8 µg/L (SE)	4.7 (0.7)	9.0 (2.3)	4.6 (1.0)	1.2 (0.6)	4.9 (0.9)	8.1 (1.2)	2.1 (0.4)
No. of women ≥ 5.8 µg/L (millions)	3.1	1.0	1.21	0.17	0.72		

[a]NHANES was not designed to provide population estimates for coastal and noncoastal areas; therefore unbiased estimates of the number of women having BHg concentrations ≥ 3.5 µg/L and to ≥ 5.8 µg/L cannot be developed.

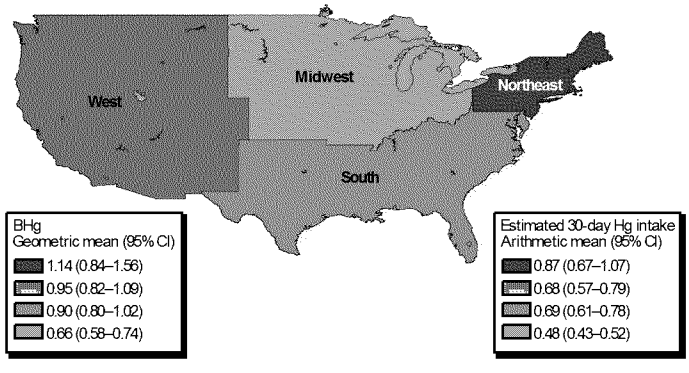

Figure 1. BHg concentration [geometric mean (95% CI) (µg/L)] and estimated 30-day dietary Hg intake [arithmetic mean (95% CI) ($\mu g/kg_{bw}$)] by U.S. Census region. CI, confidence interval.

therefore, we limited our definitions of coastal and noncoastal to follow county boundaries. We defined all counties that bordered the Pacific or Atlantic Oceans, the Gulf of Mexico, or any of the Great Lakes as coastal. Additionally, we defined counties that bordered estuaries and bays as coastal, as well as counties whose center point was within approximately 25 miles of any coast even if not directly bordering a coast. [For the list of counties, see Supplemental Material, Table 13 (http://www.ehponline.org/members/2008/11674/suppl.pdf).] We then defined the four coastal regions based on nearest body of water; for example, counties in California, Oregon, Washington, Alaska, and Hawaii that we defined as coastal were categorized as Pacific Coast. We separated noncoastal counties into four inland regions using the U.S. Census regions; for example, noncoastal counties in California, Oregon, Washington, and Alaska along with the entire states of Idaho, Montana, Wyoming, Colorado, New Mexico, Arizona, Utah, and Nevada became the West region (we classified all of Hawaii as coastal). We also designated the entire state of Florida as coastal, split between the Atlantic Coast and the Gulf of Mexico. We designated Miami-Dade County as Atlantic Coast, and Monroe County as Gulf of Mexico. These subdivisions run the risk of small sample sizes; however, the definition of coastal was sufficiently broad to avoid single primary sampling units.

Results

Table 1 shows the distributions of estimates of the number of women with BHg concentrations > 3.5 µg/L and > 5.8 µg/L, by region. Analyses indicate that between 1999 and 2004, the Northeast had the highest percentage of women with BHg concentrations above the 3.5 µg/L level of concern (> 19%), whereas the South had the largest estimated number of women (1.21 million) with ≥ 3.5 µg/L BHg because of elevated population in that region. Geometric means (Figure 1) show similar trends, with the highest BHg concentrations in the Northeast, followed by the West, South, and Midwest census regions. In the Northeast, the highest 5% of BHg concentrations exceeded 8.2 µg/L. [For full distributions, see Supplemental Material, Table 2 (http://www.ehponline.org/members/2008/11674/suppl.pdf).] When we included coastal regions in this analysis, additional spatial heterogeneity in BHg (Figure 2A) and estimated 30-day Hg intake (Figure 2B) was apparent, with elevated exposures in all coastal areas relative to their neighboring inland regions except in the Great Lakes. In the coastal areas, the highest 5% of BHg concentrations exceeded 7.2 µg/L, with the Atlantic Coast exceeding 10.9 µg/L. [For the full distributions, see Supplemental Material, Table 4 (http://www.ehponline.org/members/2008/11674/suppl.pdf).] Fish species eaten by survey participants varied by region (Figure 3), with respondents in coastal regions reporting higher frequency of consumption of fish containing higher levels of Hg. BHg concentrations were strongly associated with the frequency of fish consumption (Figure 4). BHg increased with monthly estimated consumption of fish and shellfish over the range of never/rarely to 4 or more times per week. In multiple regression modeling, women from the Atlantic ($p < 0.01$), Pacific ($p < 0.0001$), and Gulf ($p < 0.0001$) coasts had higher BHg concentrations compared with women from the inland West, whereas women from the inland Northeast and inland

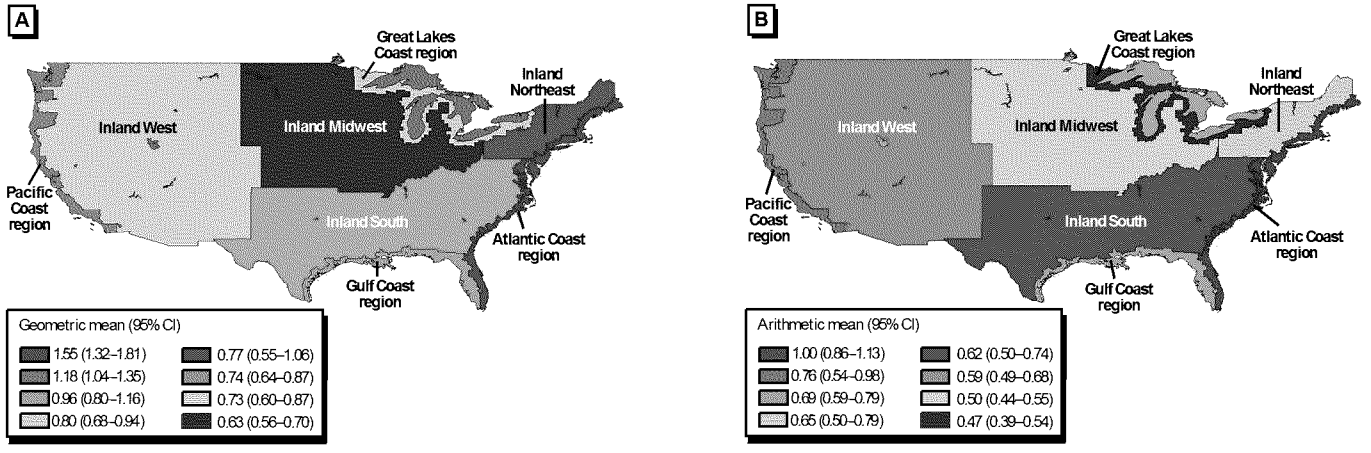

Figure 2. BHg concentration [geometric mean (95% CI) (µg/L)] (*A*) and estimated 30-day Hg intake [arithmetic mean (95% CI) (µg Hg/kg $_{bw}$)] (*B*) by coastal/inland regions. CI, confidence interval.

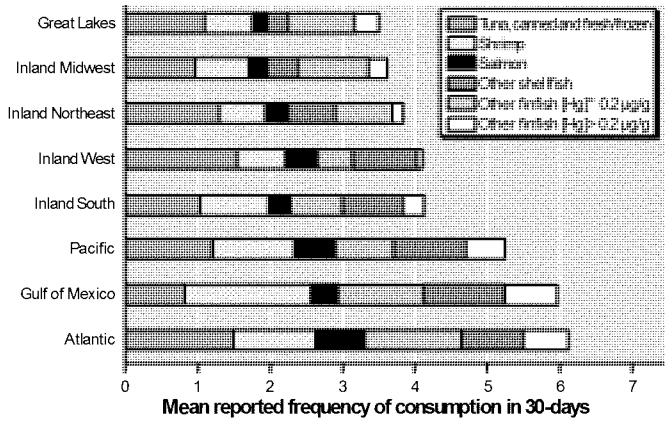

Figure 3. Species and frequency of meals consumed by geographic residence.

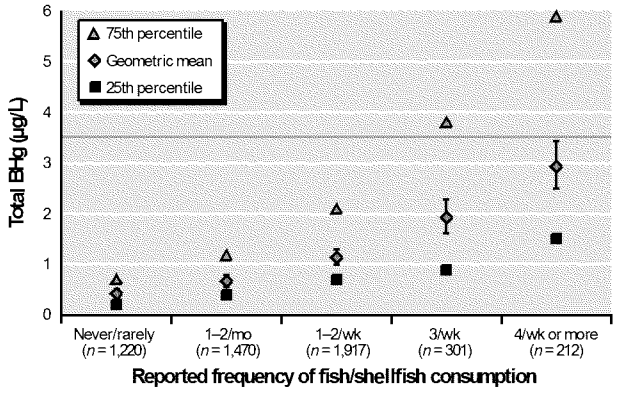

Figure 4. BHg concentration (µg/L) by estimated consumption frequency of fish and shellfish. Blue line identifies adult women's concentration associated with cord BHg ≥ 5.8 µg/L.

Midwest had significantly lower BHg levels ($p < 0.0001$). [For the full regression results, see Supplemental Material, Table 11 (http://www.ehponline.org/members/2008/11674/suppl.pdf).]

Analysis of temporal trends through simple regression modeling showed no statistically significant difference among the three sets of study years (1999–2000, 2001–2002, and 2003–2004) for BHg ($p = 0.07$), estimated 30-day Hg intake ($p = 0.11$), or reported frequency of seafood consumption ($p = 0.69$). However, in multiple regression modeling, adjusting for covariates including coastal/noncoastal residence, the years 1999–2000 had significantly higher BHg levels ($p < 0.0001$) compared with 2003–2004, and 2001–2002 had significantly lower BHg levels ($p < 0.01$) [Supplemental Material, Table 11 (http://www.ehponline.org/members/2008/11674/suppl.pdf)]. Although the analyses did not support the conclusion that there was a general downward trend in BHg concentrations over the 6-year study period, there was a decline in the upper percentiles reflecting the most highly exposed women with BHg concentrations greater than established levels of concern [Supplemental Material, Table 9 (http://www.ehponline.org/members/2008/11674/suppl.pdf)]. In addition, the percentage of examinees with BHg values ≥ 3.5 µg/L and ≥ 5.8 µg/L was much greater in 1999–2000 compared to 2001–2002 and 2003–2004 (Figure 5). We found no consistent trend in fish consumption across the study years. We observed a decrease in the 90th percentile of 30-day estimated intake of Hg through seafood consumption across the study years even though there was no similar decrease in the 90th percentile of 30-day estimated consumption of grams of fish and shellfish (Figure 6). This suggests a shift in consumption to seafood containing less Hg. We did not observe a similar pattern at the mean, suggesting that this shift in seafood consumption occurred mainly with the highest fish and shellfish consumers [Supplemental Material, Table 9 (http://www.ehponline.org/members/2008/11674/suppl.pdf)]. The RfD for Hg intake is 0.1 µg Hg/kg body weight (µg/kg$_{bw}$) per day, or 3.0 µg Hg/kg$_{bw}$ per month (30 days).

Results also showed that self-selected ethnic identity was associated with total BHg concentrations, estimated 30-day Hg intake, and frequency of either finfish or shellfish consumption. For example, BHg levels, reported frequency of seafood consumption, and 30-day Hg intakes were highest among women who designated themselves as being in the "other" category (mostly people whose ancestry is Asian, Native American, Pacific Islands, and the Caribbean Islands). [See also Supplemental Material, Tables 5–7 (http://www.ehponline.org/members/2008/11674/suppl.pdf).] Table 2 presents the percentages of women by race/ethnicity that had ≥ 3.5 and ≥ 5.8 µg/L BHg.

We identified statistically significant relationships between higher income and, respectively, increasing BHg concentration ($p < 0.0001$), estimated 30-day intake of Hg ($p = 0.008$), and 30-day frequency of finfish and shellfish consumption ($p < 0.0001$) through bivariate regressions. [For the distributions of blood total Hg, estimated Hg intake, and frequency of finfish and shellfish consumption by annual income, see Supplemental Material, Tables 6–8(http://www.ehponline.org/members/2008/11674/suppl.pdf).] In addition, women from families reporting incomes of ≥ $75,000 (the reference category) had statistically higher BHg levels than did women from families with incomes of ≤ $55,000 ($p < 0.01$). In all cases, BHg concentrations were also significantly associated with age and estimated 30-day Hg intake ($p < 0.0001$). Table 3 presents the percentage of women by annual income with ≥ 3.5 and ≥ 5.8 µg/L BHg.

In multiple regression modeling, after adjusting for other factors related to BHg, both race/ethnicity and income remained statistically significant predictors of BHg levels observed in this study [Supplemental Material, Table 11 (http://www.ehponline.org/members/2008/11674/suppl.pdf)]. Non-Hispanic blacks ($p < 0.0001$) and women grouped in the "other" racial category ($p = 0.002$) had significantly higher BHg concentrations than did non-Hispanic whites.

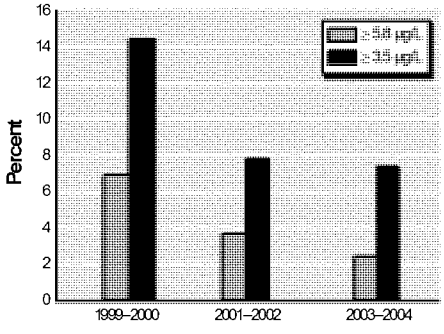

Figure 5. Percentage of women 16–49 years of age having BHg concentrations greater than those associated with exposures considered higher than the U.S. EPA's RfD for MeHg.

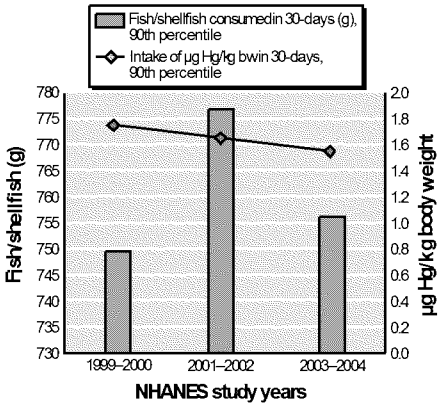

Figure 6. Ninetieth percentiles of estimated 30-day consumption of fish and shellfish (g) and estimated 30-day intake of Hg (µg Hg/kg $_{bw}$) by NHANES study year.

Discussion

Regional and coastal variation in BHg concentrations and in fish consumption. Comparisons of the distribution of BHg data with reference values aimed at protecting the fetal nervous system have been made using national-level data (Mahaffey et al. 2004). NHANES data are often used to make population estimates through application of weighting factors to variables of interest such as BHg. Population estimates for U.S. Census regions and their distribution of BHg concentrations indicate that women living in the Northeast had BHg concentrations exceeding

Table 2. Percentages of examinees and population estimates (in millions) of women with BHg concentrations ≥ 3.5 µg/L and ≥ 5.8 µg/L by race/ethnicity.

BHg	All	Mexican American	Other Hispanic	Non-Hispanic white	Non-Hispanic black	Other race[a]
Percent ≥ 3.5 µg/L (SE)	10.4 (1.0)	4.9 (0.7)	9.4 (2.7)	10.0 (1.4)	10.3 (1.7)	27.4 (3.1)
No. of women ≥ 3.5 µg/L (millions)	6.92	0.30	0.44	4.4	0.90	0.91
Percent ≥ 5.8 µg/L (SE)	4.7 (0.7)	1.4 (0.3)	2.9 (1.4)	4.6 (0.9)	4.1 (1.1)	15.7 (2.9)
No. of women ≥ 5.8 µg/L (millions)	3.1	0.08	0.14	2.0	0.36	0.52

[a]Includes people whose ancestry is Asian, Native American, Pacific Islands, and the Caribbean Islands.

Table 3. Percentages of examinees and population estimates (in millions) of women with BHg concentrations ≥ 3.5 µg/L and ≥ 5.8 µg/L by and annual income.

BHg	All	$0–$9,999	$10,000–$19,999	$20,000–$34,999	$35,000–$54,999	$55,000–$74,999	≥ $75,000
Percent ≥ 3.5 µg/L (SE)	10.4 (1.0)	4.3 (1.3)	5.4 (1.4)	6.8 (1.4)	9.6 (1.6)	10.5 (1.7)	16.2 (2.2)
No. of women ≥ 3.5 µg/L (millions)	6.92	0.18	0.40	0.80	1.11	0.92	2.72
Percent ≥ 5.8 µg/L (SE)	4.7 (0.7)	1.0 (0.5)	1.7 (0.7)	2.9 (0.8)	5.3 (1.3)	6.0 (1.4)	7.1 (1.3)
No. of women ≥ 5.8 µg/L (millions)	3.1	0.04	0.12	0.34	0.62	0.53	1.20

levels of concern more often than did women living in the South and West. The lowest Hg exposures were reported among women living in the Midwest.

Because NHANES was not designed to provide population estimates for coastal and noncoastal areas, unbiased estimates for the number of women having BHg concentrations ≥ 3.5 µg/L and ≥ 5.8 µg/L cannot be developed comparing coastal- and noncoastal-residing women. Although the following are not population estimates, they are statistics for a geographic region: Women living in coastal areas were at greater risk of having BHg concentrations ≥ 3.5 µg/L (16.25% for coastal and 5.99% for noncoastal residents) and ≥ 5.8 µg/L (8.11% for coastal and 2.06% for noncoastal residents). Women living near the coastal areas have approximately three to four times greater risk of exceeding acceptable levels of Hg exposure than do noncoastal-dwelling women. There may be some bias in these results due to the weighting issues (see "Materials and Methods"); however, we do not believe that this bias is a major factor underlying these great differences.

MeHg exposures exceeding health-based standards, including U.S. EPA's RfD (Rice et al. 2003), occurred more commonly among women living in coastal areas. These health-based standards were based on avoiding MeHg-associated delays and deficits in neurologic development of children after *in utero* exposure to MeHg (Mergler et al. 2007; Rice et al. 2003). At higher exposures to MeHg, including the highest concentrations reported during these survey years, the women themselves may risk adverse neuropsychological and neurobehavioral outcomes (Mergler et al. 2007).

Within the United States, people living in coastal areas consume more fish and shellfish than do those living in noncoastal areas and consume fish with higher Hg concentrations. Reports from New York City (McKelvey et al. 2007) and Florida (Denger et al. 1994; Karouna-Renier et al. 2008) support our identification of higher Hg exposures in U.S. coastal areas. This is part of a worldwide pattern. An overall pattern of higher BHg levels has also been reported among people living on U.S. islands [Hawaii (Sato et al. 2006)] and territories [e.g., Puerto Rico (Ortiz-Roque and López-Rivera 2004)]. A similar pattern has been repeated in other islands [Bermuda (Dewailly and Pereg 2004; see also Bermuda Biological Stations for Research 2004), Fiji (Kumar et al. 2006), Seychelles (Myers et al. 2007), and Tahiti (Chateau-Degat 2005; Dewailly et al. 2008)] compared with inland populations. Among these island populations, BHg concentrations at the upper end of the distribution fall into the range of 50 µg/L (~ 250 nmol/L) and higher (Chateau-Degat 2005). In Bermuda, cord BHg concentrations as high as 160 nmol/L (~ 35 µg/L) have been reported (arithmetic mean, 41.3 ± 4.7 nmol/L or 8.0 ± 1.0 µg/L) (Dewailly and Pereg 2004; see also Bermuda Biological Stations for Research 2004).

Higher BHg concentrations in the U.S. Northeast found in this study reflect , in part, more frequent fish and shellfish consumption. Additional variability may be a function of differences in Hg concentrations among species and geographic regions (Sunderland 2007). For example, recent information on "hot spots" for Hg in wildlife tissues (Evers et al. 2007) could be associated with higher Hg concentrations for locally obtained fish. One limitation of the present analysis was the use of a fish-species–specific mean Hg concentration (i.e., nondistributional values) to estimate individual exposure. Although most fish consumed by the U.S. population is not locally obtained (i.e., commercially obtained from diverse regions and countries) (Sunderland 2007), analytical results showing geographic differences in the distribution of BHg could reflect higher Hg concentrations in locally obtained fish within the Northeast states.

Ethnic group variation on fish intake and BHg concentrations. Ethnic origins were associated with Hg exposures with those designated as "other" (i.e., Asian, Pacific and Caribbean Islander, Native American, Alaska Native, multiracial, and unknown race) having higher BHg concentrations. From additional studies, people of Asian descent whose food choices are influenced by Asian dietary patterns (Kudo et al. 2000; Sechena et al. 2003) tended to consume fish more frequently, in greater variety, and in greater quantity than did non-Asians. The ethnic diversity of the U.S. population is well known. As of 1997, 61% of the Asian population living in the United States was foreign-born (Council of Economic Advisors 1999). By comparison with overall U.S. data, higher BHg concentrations among Asians and islanders were reported for Taiwan (Hsu et al. 2007), Cambodia (Agusa et al. 2007), Fiji (Kumar et al. 2006), and Tahiti (Dewailly et al. 2008).

Within the United States, fish and shellfish consumption, predicting Hg exposure described previously, varies widely, in part a reflection of ethnicity. For example, Asian countries [e.g., Cambodia (Agusa et al. 2007), Taiwan (Hsu et al. 2007; Soong et al. 1991), Japan (Murata et al. 2007; Sakamoto et al. 2007)], island nations [e.g., Bermuda (Dewailly and Pereg 2004; see also Bermuda Biological Stations for Research 2004), Seychelles (Myers et al. 2007), Tahiti (Chateau-Degat 2005), Taiwan (Hsu et al. 2007; Soong et al. 1991), Japan (Murata et al. 2007; Sakamoto et al. 2007)], and some European countries [e.g., Spain (Falcó et al. 2006; Herreros et al. 2008) and the Faroe Islands (Weihe et al. 1996)] have reported fish/shellfish consumption levels greater than average worldwide consumption (World Health Organization 2008).

Income differences in association with fish intake and BHg concentrations. In contrast to some other environmental exposures [e.g., higher blood lead concentrations] (Mahaffey et al. 1982), BHg concentrations increased with income. This is consistent with other studies in which women from higher income groups were at greater risk of MeHg exposure, as were women living in urban areas (Hightower and Moore 2003; Saint-Phard and Van Dorsten 2006).

Interactions between income and ethnic group. A more complex association between income and racial/ethnic group may also exist. According to the 1990 U.S. Census (U.S. Census Bureau 2008), the median family income of Japanese-American families exceeded that of non-Hispanic white families. By contrast, the income of Cambodian-American families was lower than that of black families. We could not address whether there is an interaction between belonging to the category designated as "other" and higher income within the NHANES data on BHg levels available at this time, because of sample size limitations.

Time trends in Hg exposure absent changes in total fish consumption. Our analysis of 30-day Hg intake indicated that there was no consistent trend in fish consumption by women of childbearing age over the 6-year period between 1999 and 2004. Our evaluation of NHANES fish intake data indicated no differences in the mean frequency or amount of particular fish and shellfish species consumed. However, the estimated 30-day Hg intake decreased at the 90th percentile and higher, whereas total fish consumption did not, which suggests a shift in fish species consumed. The BHg data indicated a reduction of the higher end of the distribution of BHg between the first 2-year interval (the 1999 and 2000 examinees) compared with the subsequent 4-year interval (the 2001–2004 examinees).

The basis for these differences could possibly reflect spillover from the federal fish advisory program (U.S. EPA 2008b) in terms of total fish and shellfish consumption. A recent analysis of a nationally representative study specifically addressing fish-consumption patterns did not support this suggestion (Bradbury 2007).

The four fish species listed in the federal advisory [swordfish, shark, tilefish, and king mackerel (U.S. EPA 2008b)] were rarely reported by the 5,465 women in this analysis. It is clear that these four fish species contributed little to Hg exposure in this general population of U.S. women. Individual

states with higher Hg exposures [e.g., Hawaii (Sato et al., 2006), Florida (Karouna-Renier et al. 2008)] and greater fish consumption [Florida (Denger et al. 1994)] have substantially broader fish consumption advisories (e.g., Hawaii and Florida) aimed at reducing Hg exposure from high-Hg–containing species obtained locally (Florida Department of Health 2007; U.S. EPA 2008b). Despite the federal advisory's emphasis on four species of highly contaminated fish (U.S. EPA 2008b) and the states' emphasis on game fish, the most commonly consumed finfish in the United States is tuna. Interpretation of Hg exposure from tuna was complicated by the specific wording of the dietary questions asked of the NHANES examinees, which did not differentiate between light or skipjack tuna and albacore tuna. The latter contains approximately three times more Hg than does the former: 0.38 µg/g for frozen and fresh tuna, 0.35 µg/g for canned albacore, and 0.12 µg/g for canned light tuna (Mahaffey et al. 2008).

Changes in MeHg exposure over time. During the past decade, the U.S. EPA initiated substantial interventions aimed to reduce Hg releases and exposures (U.S. EPA 2008a) and issued advisories to limit consumption of high-Hg fish (U.S. EPA 2008b). Because of worldwide atmospheric distribution and subsequent deposition of Hg, local conditions and locally caught fish are not the main contributors to Hg intake for most people (Sunderland 2007). Although there are economic indications that consumption of some species of fish may have decreased in response to these advisories (Shimshack et al. 2007), Hg exposures may not follow a similar time trend despite regulatory efforts to reduce Hg exposures. A recent analysis of a nationally representative study specifically addressing fish-consumption patterns did not support this suggestion (Bradbury 2007). Our analysis of NHANES data calculating 30-day Hg intake indicated that there was no consistent trend in fish consumption by women of childbearing age over the 6-year period between 1999 and 2004.

Conclusions

Significant geographic differences in BHg concentrations occurred within the United States: We found highest exposures in coastal areas and the Northeast census region. In the Northeast, 19% of women had BHg concentrations ≥ 3.5 µg/L. The highest 5% of BHg concentrations exceeded 8.2 µg/L in the Northeast and 7.2 µg/L in coastal areas, concentrations more than twice the 3.5 µg/L level of concern. BHg levels are predicted by the quantity and type of fish consumed. Over the 6-year period (1999–2004), the frequency of elevated BHg levels among women of childbearing age declined without a significant change in quantities of fish and shellfish consumed. This pattern suggests a more discerning series of choices in type of fish eaten rather than an overall reduction in fish consumption. Within all geographic regions, women at highest risk of elevated Hg exposures were more affluent and more likely to be of Asian or island ethnicity.

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Blood Methyl Mercury (2011 - 2012)

Geometric mean and selected percentiles of blood concentrations (in µg/L) for the U.S. population from the National Health and Nutrition Examination Survey.

	Survey years	Geometric mean (95% conf. interval)	Selected percentiles (95% confidence interval) 50th	75th	90th	95th	Sample size
Total	11-12	**.498** (.423-.587)	**.480** (.400-.570)	**1.25** (.950-1.61)	**2.81** (2.29-3.55)	**4.43** (3.46-5.49)	7841
Age group							
1-5 years	11-12	*	**.140** (.120-.170)	**.270** (.220-.350)	**.540** (.420-.780)	**.970** (.590-1.14)	657
6-11 years	11-12	**.209** (.182-.241)	**.180** (.150-.220)	**.400** (.330-.490)	**.820** (.630-1.06)	**1.34** (.940-1.84)	1044
12-19 years	11-12	**.276** (.237-.322)	**.270** (.210-.310)	**.570** (.460-.670)	**1.27** (.870-1.67)	**2.15** (1.40-2.81)	1121
20 years and older	11-12	**.624** (.523-.746)	**.610** (.500-.760)	**1.53** (1.18-2.00)	**3.28** (2.56-4.31)	**4.97** (3.91-6.89)	5019
Gender							
Males	11-12	**.509** (.433-.598)	**.490** (.400-.590)	**1.30** (.990-1.62)	**2.84** (2.29-3.68)	**4.77** (3.44-6.74)	3925
Females	11-12	**.489** (.413-.580)	**.470** (.380-.560)	**1.19** (.900-1.61)	**2.72** (2.18-3.46)	**3.99** (3.28-4.99)	3916
Race/ethnicity							
Mexican Americans	11-12	**.320** (.264-.387)	**.330** (.260-.410)	**.610** (.500-.770)	**1.23** (.920-1.40)	**1.66** (1.33-2.06)	1058
Non-Hispanic blacks	11-12	**.517** (.392-.681)	**.510** (.380-.660)	**1.13** (.750-1.61)	**2.37** (1.66-3.08)	**3.63** (2.57-5.16)	2170
Non-Hispanic whites	11-12	**.478** (.392-.583)	**.470** (.360-.580)	**1.25** (.870-1.69)	**2.76** (2.06-3.69)	**4.24** (2.92-6.38)	2477
All Hispanics	11-12	**.429** (.350-.525)	**.420** (.340-.520)	**.890** (.700-1.17)	**1.81** (1.39-2.46)	**2.94** (2.19-3.71)	1902
Asians	11-12	**1.58** (1.29-1.94)	**2.16** (1.68-2.55)	**4.35** (3.64-5.13)	**7.57** (6.21-8.61)	**10.5** (8.48-12.5)	997

Limit of detection (LOD, see Data Analysis section) for Survey year 11-12 is 0.12.
< LOD means less than the limit of detection, which may vary for some chemicals by year and by individual sample.
* Not calculated: proportion of results below limit of detection was too high to provide a valid result.

Biomonitoring Summary: http://www.cdc.gov/biomonitoring/Mercury_BiomonitoringSummary.html
Factsheet: http://www.cdc.gov/biomonitoring/Mercury_FactSheet.html

To: Kavlock, Robert[Kavlock.Robert@epa.gov]
Cc: Gwinn, Maureen[gwinn.maureen@epa.gov]
From: Deener, Kathleen
Sent: Mon 10/26/2015 5:53:53 PM
Subject: FW: information on Hg and fish for today's discussion
spreadsheet explanation 10-20-15_v2.docx
Copy of Example Calculations 10-20-15-rev.xlsx

Bob – I thought you'd be interested in seeing this. Can give you some additional background if you want.

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Flowers, Lynn
Sent: Tuesday, October 20, 2015 12:12 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; Phillips, Linda <Phillips.Linda@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>
Subject: information on Hg and fish for today's discussion

Kacee:

There are two attachments for today's check in meeting with you:

1) A spreadsheet of calculations as requested (note that there are two tabs), and

2) A write up of the analysis and results.

I also have a short list of issues to note:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lynn Flowers, PhD, DABT

Associate Director for Health

National Center for Environmental Assessment

US EPA

Washington, DC

703-347-8537

To: Phillips, Linda[Phillips.Linda@epa.gov]
Cc: Bussard, David[Bussard.David@epa.gov]; Bierwagen, Britta[Bierwagen.Britta@epa.gov]
From: Deener, Kathleen
Sent: Tue 10/4/2016 7:39:08 PM
Subject: FW: Changes to fish advice
Preview summary of peer review comments.docx
FISH_CHART_H_9.22.16.pdf
Ex. 5 - Deliberative Process .docx

Hi Linda –

Thank you for your help last year in providing comments on the proposed changes to the EPA/FDA fish consumption advice. The draft advice has been peer reviewed, Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process I'm sharing these revised materials with you as an FYI, and I'm also passing along a thank you from Tom Burke for helping with this last year.

Thanks again!

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Larimer, Lisa
Sent: Monday, September 26, 2016 12:18 AM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Subject: Changes to fish advice

Hi Kacee,

Ex. 6 - Personal Privacy

office for most of Monday. I'm including a summary that I ginned up of major changes to the fish advice since we last briefed Dr. Burke in October 2015 and the latest version of the fish chart. The workgroup is still revising other materials. Because I don't have the final version of the peer review document yet that I could send you, I'm sharing a summary of the peer review comments that I had quickly pulled together for my managers when the comments first came in. Please let me know what else I can send you to help, and please let me know if you see areas that are still issues of concern for your group.

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Smith, Kelley[Smith.Kelley@epa.gov]; Osaka, Anna[Osaka.Anna@epa.gov]
From: Deener, Kathleen
Sent: Wed 10/21/2015 3:10:21 PM
Subject: FW: information on Hg and fish for today's discussion
spreadsheet explanation 10-20-15_v2.docx
Copy of Example Calculations 10-20-15-rev.xlsx

Here are the briefing materials for Monday's meeting on fish and mercury. Tom has color copies of both already, but please also include in his briefing book. All tabs of the spreadsheet need to be printed, and all materials should be printed in color.

Thanks!

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Flowers, Lynn
Sent: Tuesday, October 20, 2015 12:12 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; Phillips, Linda <Phillips.Linda@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>
Subject: information on Hg and fish for today's discussion

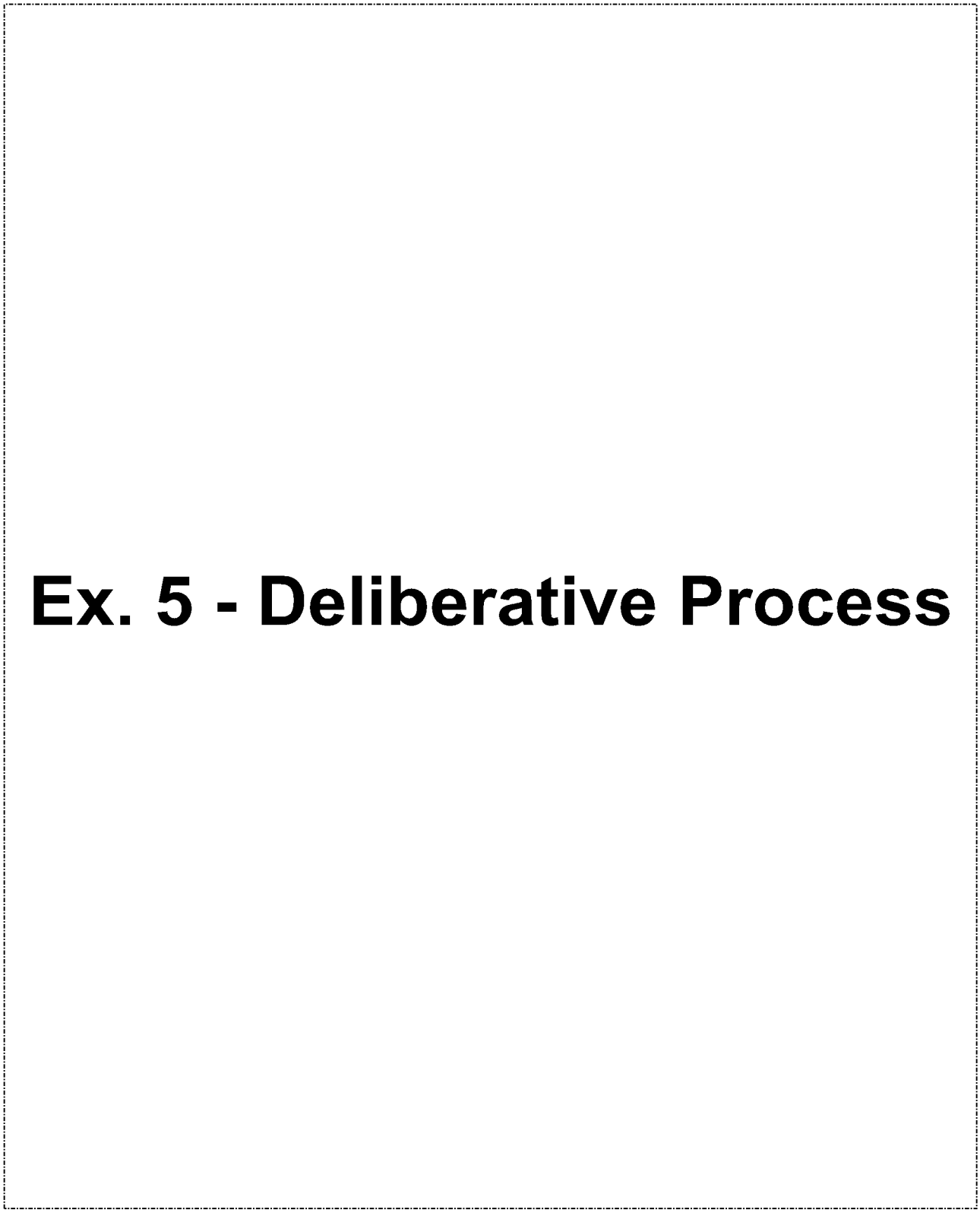
Kacee:

There are two attachments for today's check in meeting with you:

1) A spreadsheet of calculations as requested (note that there are two tabs), and

2) A write up of the analysis and results.

I also have a short list of issues to note:



Ex. 5 - Deliberative Process

Lynn Flowers, PhD, DABT

Associate Director for Health

National Center for Environmental Assessment

US EPA

Washington, DC

703-347-8537

To: Burke, Thomas[Burke.Thomas@epa.gov]
From: Deener, Kathleen
Sent: Wed 12/23/2015 9:45:54 PM
Subject: FW: Fish Advice - Input Requested on Peer Review

Tom – pasted below is the information from the Peer Review Handbook:
http://www.epa.gov/sites/production/files/2015-09/documents/final_epa_peer_review_handbook-_4th_ed_091415_dummy_link.pdf

You, Tom S, Lynn and I had talked about the benefits of a panel peer review, v Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

In terms of charge questions, I think the following be addressed:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Beauvais, Joel
Sent: Wednesday, December 23, 2015 4:23 PM
To: Burke, Thomas <Burke.Thomas@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>
Subject: Fish Advice - Input Requested on Peer Review

Hi, Tom and KC – As you know, we're making some progress on the fish advice and trying to reach agreement with FDA on the peer review. I spoke to Jeremy Sharp this afternoon, Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

We (OW) can draft up proposed charge questions and process requirements for the peer review

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process for your review and markup, but it would be helpful to get some input from you on the front end regarding the scope of charge questions that you think is essential. Could you provide us with some guidance on that at your earliest convenience?

Ex. 5 - Deliberative Process

Joel

To: Gentry, Nathan[Gentry.Nathan@epa.gov]
From: Deener, Kathleen
Sent: Wed 6/22/2016 2:19:40 PM
Subject: Fwd: Final Seafood Advice
Revised Peer Review Charge_4-14-16_final.docx
ATT00001.htm
PeerReviewChargeQsDRAFT_01 11 16.docx
ATT00002.htm

Would you mind printing two copies of the attached documents? I will come out and grab them at 10:30.

Sent from my iPhone

Begin forwarded message:

From: "Beauvais, Joel" <Beauvais.Joel@epa.gov>
Date: June 21, 2016 at 11:12:52 PM EDT
To: "Burke, Thomas" <Burke.Thomas@epa.gov>, "Deener, Kathleen" <Deener.Kathleen@epa.gov>
Cc: "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>, "Campbell, Ann" <Campbell.Ann@epa.gov>
Subject: FW: Final Seafood Advice

Hi, Tom – See incoming below from Jeremy Sharp at FDA re seafood advice. They would like to proceed with the peer review, **Ex. 5 - Deliberative Process** Ex. 5 - Deliberative Process I have included Betsy's take on this as well. Can I get your input/advice on this at your earliest convenience so we can get back to FDA? Thanks in advance.

Joel

From: Southerland, Elizabeth
Sent: Monday, June 20, 2016 1:51 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov>; Barash, Shari <Barash.Shari@epa.gov>; Larimer, Lisa <Larimer.Lisa@epa.gov>; Wathen, John <Wathen.John@epa.gov>
Subject: Final Seafood Advice

We reviewed the revised draft charge from FDA (and corresponding email from Jeremy) and compared it to the version we sent to them in January (both versions are attached).

Overall we do not have any issues with FDA's changes to the charge to the peer reviewers.

For your information, we found the following changes:

Ex. 5 - Deliberative Process

From: Sharp, Jeremy [mailto:Jeremy.Sharp@fda.hhs.gov]
Sent: Friday, June 17, 2016 12:09 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Subject: Final Seafood Advice

Joel, I apologize for the long delay in my engagement of you on this. In our in-person meeting about EPA's concerns and proposed changes to the FDA-EPA fish advice, you outlined 3 general areas of concern. We are most anxious to move forward to finalize the advice, and in the time since our meeting have worked to address and respond to your requests as noted below.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process We look forward to hearing from you as soon as possible.

Jeremy Sharp

Deputy Commissioner

Policy, Planning, Legislation, and Analysis

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, Maryland 20993

301-796-8770

To: Burke, Thomas[Burke.Thomas@epa.gov]
From: Deener, Kathleen
Sent: Fri 12/18/2015 7:06:52 PM
Subject: Re: Fish Advice Update - Need feedback by next Monday or Tuesday

Yes - will do.

Sent from my iPhone

On Dec 18, 2015, at 1:53 PM, Burke, Thomas <Burke.Thomas@epa.gov> wrote:

> Could you talk to the team and mull this over. Too distracted....
>
> Thomas A. Burke, PhD, MPH
> Deputy Assistant Administrator
> EPA Science Advisor
> Office of Research and Development
> 202-564-6620
> burke.thomas@epa.gov
>
> Begin forwarded message:
>
> **From:** "Beauvais, Joel" <Beauvais.Joel@epa.gov>
> **Date:** December 18, 2015 at 1:50:27 PM EST
> **To:** "Burke, Thomas" <Burke.Thomas@epa.gov>
> **Subject: Fish Advice Update - Need feedback by next Monday or Tuesday**
>
> Hi, Tom – Below is a read-out on the state of play regarding staff discussions on the Fish Advice. I have a call with Jeremy next week at which I can discuss the messaging piece and process forward. I would like to get feedback from you on at least two items (and any others that you'd like to discuss). I'd welcome your thoughts on these or any of the below. I am talking to Jeremy next Wednesday, so would like to get feedback from you on this beforehand. If we need to do a call or meeting, I am happy to set up.

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

OW Staff Update:

Note for 1/5/15 meeting with FDA:

OST will work with schedulers for Jeremy Sharpe, Tom Burke, and Joel Beauvais to move the Jan. 5 meeting. The workgroup hopes to have an agreed upon path forward and supporting documentation by the week of Jan. 18 and will try to schedule a meeting for that week.

Status of EPA's requests:

On Monday Dec. 14, OST staff traveled to FDA Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

In response to the 3 Ex. 5 - Deliberative Process

1. **Messaging:** Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

2. **Data:** Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

To: Fegley, Robert[Fegley.Robert@epa.gov]
Cc: Schoeny, Rita[Schoeny.Rita@epa.gov]
From: Deener, Kathleen
Sent: Mon 9/28/2015 10:18:17 PM
Subject: RE: Follow-up Information on EPA-FDA Fish Advice

Thanks Bob! I just left a voicemail message to give you some more context about my question on Ex. 5 - Deliberative Process

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Fegley, Robert
Sent: Monday, September 28, 2015 6:10 PM
To: Deener, Kathleen
Cc: Schoeny, Rita
Subject: FW: Follow-up Information on EPA-FDA Fish Advice

Kacee, I have a call into Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Hisel-Mccoy, Sara
Sent: Monday, September 28, 2015 5:27 PM
To: Fegley, Robert

Cc: Deener, Kathleen; Hauchman, Fred
Subject: Re: Follow-up Information on EPA-FDA Fish Advice

Great. ThAnks for the heads up. Kacee also had a question about Ex. 5 - Deliberative Process that we are working on. Do you know, are there any other outstanding questions you have? Thanks, Sara

Sara Hisel-McCoy

Standards and Health Protection Division

202 566-1649

On Sep 28, 2015, at 5:24 PM, Fegley, Robert <Fegley.Robert@epa.gov> wrote:

> Sara, Kacee did share this with me earlier this afternoon.
>
> **From:** Hauchman, Fred
> **Sent:** Monday, September 28, 2015 5:23 PM
> **To:** Hisel-Mccoy, Sara
> **Cc:** Deener, Kathleen; Southerland, Elizabeth; Barash, Shari; Larimer, Lisa; Fegley, Robert
> **Subject:** Re: Follow-up Information on EPA-FDA Fish Advice
>
> Sara,
>
> FYI, I'm out of the office this week. Bob Fegley is coordinating our input with Kacee.
>
> Fred
>
> Sent from my iPhone
>
> On Sep 28, 2015, at 5:53 PM, Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov> wrote:
>
> > KaCee and Fred –
> >
> > Hello. We're following up with more information related to the FDA-EPA fish advice. Also, as Betsy mentioned in a previous note, FDA is meeting with the HHS Secretary on Wednesday so we would very much like to get feedback as soon as possible.

Sara

Focus on mercury

In the meeting last week, we heard the concern that the advice is limited to only mercury. However, focusing on mercury in our joint advice is on target because mercury collects in the muscle tissue (fillet) and nothing in the preparation/cooking process can be done to reduce risks from mercury. Consumers can reduce risks from PCBs and other organic contaminants through the cleaning and cooking process because those contaminants collect in the fatty tissues, a large portion of which can be removed when the fish are prepped for cooking. The Q&A for the FDA-EPA fish advice discusses removing skin, belly fat, and internal organs before cooking. In addition, most of the state advisories for locally caught fish are for mercury (81% in 2011). Fifty states monitor for mercury and 39 monitor for PCBs.

Ex. 5 - Deliberative Process

The water program uses mean mercury concentrations. The FDA-EPA fish advice is based upon mean mercury concentrations in commercial fish and how often those fish can be eaten without exceeding the RfD. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

As a sensitivity analysis, we Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Other considerations

Ex. 5 - Deliberative Process

FINFISH/SHELLFISH	Mean Hg conc (ppm)
ANCHOVIES	0.02
BLUEFISH	0.37
BUFFALO FISH	0.14
CARP	0.11
CATFISH	0.02
CLAM	0.01
COD	0.11
CRAB	0.06
CRAWFISH	0.03
CROAKER, ATLANTIC	0.07
CROAKER, WHITE	0.29
FLATFISH: FLOUNDER	0.05

Ex. 5 - Deliberative Process

FLATFISH: PLAICE	0.04
FLATFISH: SOLE	0.08
GROUPER	0.45
HADDOCK	0.06
HAKE	0.08
HALIBUT	0.24
HERRING	0.08
LOBSTER, AMERICAN	0.11
LOBSTER, SPINY	0.09
MAHI MAHI	0.18
MARLIN	0.49
MONKFISH	0.16
MULLET	0.05
ORANGE ROUGHY	0.57
OYSTER	0.01
PERCH, FRESHWATER	0.15
PERCH, OCEAN	0.12
PICKEREL	0.09
POLLOCK	0.03
ROCKFISH	0.23
SABLE FISH	0.36
SALMON	0.02
SALMON, CANNED	0.01
SARDINE	0.01
SCALLOP	0.00
SCORPIONFISH	0.23
SEA BASS, BLACK	0.13
SEA BASS, CHILEAN	0.35
SEA BASS, STRIPED	0.07
SHAD	0.04

Ex. 5 - Deliberative Process

SHARK	0.98
SHEEPSHEAD	0.09
SHRIMP	0.01
SMELT	0.08
SNAPPER	0.17
SQUID	0.02
SWORDFISH	1.00
TILAPIA	0.01
TILEFISH, ATLANTIC	0.14
TROUT, FRESHWATER	0.07
TUNA, CANNED (ALBACORE)	0.35
TUNA, CANNED (LIGHT)	0.13
TUNA, FR/FZN ALBACORE	0.36
TUNA, FR/FZN BIGEYE	0.69
TUNA, FR/FZN SKIPJACK	0.14
TUNA, FR/FZN YELLOWFIN	0.35
WEAKFISH (SEA TROUT)	0.23
WHITEFISH	0.09
WHITING	0.05

Ex. 5 - Deliberative Process

To: Fegley, Robert[Fegley.Robert@epa.gov]
From: Deener, Kathleen
Sent: Mon 9/28/2015 7:27:05 PM
Subject: FW: Follow-up Information on EPA-FDA Fish Advice

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Hisel-Mccoy, Sara
Sent: Monday, September 28, 2015 1:53 PM
To: Deener, Kathleen; Hauchman, Fred
Cc: Southerland, Elizabeth; Barash, Shari; Larimer, Lisa
Subject: Follow-up Information on EPA-FDA Fish Advice

KaCee and Fred –

Hello. We're following up with more information related to the FDA-EPA fish advice. Also, as Betsy mentioned in a previous note, FDA is meeting with the HHS Secretary on Wednesday so we would very much like to get feedback as soon as possible.

Sara

Focus on mercury

In the meeting last week, we heard the concern that the advice is limited to only mercury. However, focusing on mercury in our joint advice is on target because mercury collects in the muscle tissue (fillet) and nothing in the preparation/cooking process can be done to reduce risks

from mercury. Consumers can reduce risks from PCBs and other organic contaminants through the cleaning and cooking process because those contaminants collect in the fatty tissues, a large portion of which can be removed when the fish are prepped for cooking. The Q&A for the FDA-EPA fish advice discusses removing skin, belly fat, and internal organs before cooking. In addition, most of the state advisories for locally caught fish are for mercury (81% in 2011). Fifty states monitor for mercury and 39 monitor for PCBs.

-

Ex. 5 - Deliberative Process

The water program uses mean mercury concentrations. The FDA-EPA fish advice is based upon mean mercury concentrations in commercial fish and how often those fish can be eaten without exceeding the RfD. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

As a sensitivity analysis, we Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

-

Other considerations

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

FINFISH/SHELLFISH	Mean Hg conc (ppm)
ANCHOVIES	0.02
BLUEFISH	0.37
BUFFALO FISH	0.14
CARP	0.11
CATFISH	0.02
CLAM	0.01
COD	0.11
CRAB	0.06
CRAWFISH	0.03
CROAKER, ATLANTIC	0.07
CROAKER, WHITE	0.29
FLATFISH: FLOUNDER	0.05
FLATFISH: PLAICE	0.04
FLATFISH: SOLE	0.08
GROUPER	0.45
HADDOCK	0.06
HAKE	0.08
HALIBUT	0.24
HERRING	0.08
LOBSTER, AMERICAN	0.11
LOBSTER, SPINY	0.09
MAHI MAHI	0.18

Ex. 5 - Deliberative Process

MARLIN	0.49
MONKFISH	0.16
MULLET	0.05
ORANGE ROUGHY	0.57
OYSTER	0.01
PERCH, FRESHWATER	0.15
PERCH, OCEAN	0.12
PICKEREL	0.09
POLLOCK	0.03
ROCKFISH	0.23
SABLE FISH	0.36
SALMON	0.02
SALMON, CANNED	0.01
SARDINE	0.01
SCALLOP	0.00
SCORPIONFISH	0.23
SEA BASS, BLACK	0.13
SEA BASS, CHILEAN	0.35
SEA BASS, STRIPED	0.07
SHAD	0.04
SHARK	0.98
SHEEPSHEAD	0.09
SHRIMP	0.01
SMELT	0.08
SNAPPER	0.17
SQUID	0.02
SWORDFISH	1.00
TILAPIA	0.01
TILEFISH, ATLANTIC	0.14
TROUT, FRESHWATER	0.07
TUNA, CANNED (ALBACORE)	0.35
TUNA, CANNED	

Ex. 5 - Deliberative Process

(LIGHT) TUNA, FR/FZN ALBACORE	0.36
TUNA, FR/FZN BIGEYE	0.69
TUNA, FR/FZN SKIPJACK	0.14
TUNA, FR/FZN YELLOWFIN	0.35
WEAKFISH (SEA TROUT)	0.23
WHITEFISH	0.09
WHITING	0.05

Ex. 5 - Deliberative Process

To: Kime, Robin[Kime.Robin@epa.gov]
From: Deener, Kathleen
Sent: Mon 9/28/2015 3:28:04 PM
Subject: FW: Ex. 5 - Deliberative Process for fish advice

FYI

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Southerland, Elizabeth
Sent: Saturday, September 26, 2015 6:59 AM
To: Deener, Kathleen; Hauchman, Fred
Cc: Hisel-Mccoy, Sara
Subject: Fwd: Ex. 5 - Deliberative Process for fish advice

Ex. 5 - Deliberative Process

Sent from my iPhone

Begin forwarded message:

From: "Hisel-Mccoy, Sara" <Hisel-McCoy.Sara@epa.gov>

Date: September 25, 2015 at 6:38:18 PM EDT
To: "Larimer, Lisa" <Larimer.Lisa@epa.gov>, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Cc: "Barash, Shari" <Barash.Shari@epa.gov>, "Wathen, John" <Wathen.John@epa.gov>
Subject: Re: Ex. 5 - Deliberative Process **for fish advice**

Thank you so much, Lisa. Betsy-as you requested.

Sara Hisel-McCoy

Standards and Health Protection Division

202 566-1649

On Sep 25, 2015, at 5:49 PM, Larimer, Lisa <Larimer.Lisa@epa.gov> wrote:

In the table below I'm showing the mercury concentrations by fish type Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

FINFISH/SHELLFISH	Mean Hg conc (ppm)
ANCHOVIES	0.02
BLUEFISH	0.37
BUFFALO FISH	0.14
CARP	0.11
CATFISH	0.02
CLAM	0.01
COD	0.11
CRAB	0.06
CRAWFISH	0.03
CROAKER, ATLANTIC	0.07
CROAKER, WHITE	0.29
FLATFISH: FLOUNDER	0.05
FLATFISH: PLAICE	0.04

Ex. 5 - Deliberative Process

FLATFISH: SOLE	0.08
GROUPER	0.45
HADDOCK	0.06
HAKE	0.08
HALIBUT	0.24
HERRING	0.08
LOBSTER, AMERICAN	0.11
LOBSTER, SPINY	0.09
MAHI MAHI	0.18
MARLIN	0.49
MONKFISH	0.16
MULLET	0.05
ORANGE ROUGHY	0.57
OYSTER	0.01
PERCH, FRESHWATER	0.15
PERCH, OCEAN	0.12
PICKEREL	0.09
POLLOCK	0.03
ROCKFISH	0.23
SABLE FISH	0.36
SALMON	0.02
SALMON, CANNED	0.01
SARDINE	0.01
SCALLOP	0.00
SCORPIONFISH	0.23
SEA BASS, BLACK	0.13
SEA BASS, CHILEAN	0.35
SEA BASS, STRIPED	0.07
SHAD	0.04
SHEEPSHEAD	0.09
SHRIMP	0.01
SMELT	0.08
SNAPPER	0.17
SQUID	0.02
SWORDFISH	1.00
TILAPIA	0.01
TILEFISH, ATLANTIC	0.14
TROUT, FRESHWATER	0.07
TUNA, CANNED (ALBACORE)	0.35
TUNA, CANNED (LIGHT)	0.13
TUNA, FR/FZN ALBACORE	0.36

Ex. 5 - Deliberative Process

TUNA, FR/FZN BIGEYE	0.69
TUNA, FR/FZN SKIPJACK	0.14
TUNA, FR/FZN YELLOWFIN	0.35
WEAKFISH (SEA TROUT)	0.23
WHITEFISH	0.09
WHITING	0.05

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

To: Burke, Thomas[Burke.Thomas@epa.gov]
From: Deener, Kathleen
Sent: Fri 9/25/2015 9:01:42 PM
Subject: Re: Ex. 5 - Deliberative Process

Sounds good.
I'll be curious to see the results Ex. 5 - Deliberative Process

Agree on Ex. 5 - Deliberative Process

Have a good weekend!

Sent from my iPhone

On Sep 25, 2015, at 4:59 PM, Burke, Thomas <Burke.Thomas@epa.gov> wrote:

We can discuss on Monday. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Thomas A. Burke, PhD, MPH
Deputy Assistant Administrator
EPA Science Advisor
Office of Research and Development
202-564-6620
burke.thomas@epa.gov

On Sep 25, 2015, at 4:55 PM, Deener, Kathleen <Deener.Kathleen@epa.gov> wrote:

Sent from my iPhone

Begin forwarded message:

From: "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Date: September 25, 2015 at 3:53:36 PM EDT
To: "Deener, Kathleen" <Deener.Kathleen@epa.gov>, "Hauchman, Fred" <hauchman.fred@epa.gov>
Cc: "Hisel-Mccoy, Sara" <Hisel-McCoy.Sara@epa.gov>
Subject: Fwd: Ex. 5 - Deliberative Process

KC, Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process Please show Tom Burke Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Sent from my iPhone

Begin forwarded message:

From: "Hisel-Mccoy, Sara" <Hisel-McCoy.Sara@epa.gov>
Date: September 25, 2015 at 3:32:46 PM EDT
To: "Larimer, Lisa" <Larimer.Lisa@epa.gov>, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Cc: "Barash, Shari" <Barash.Shari@epa.gov>, "Wathen, John" <Wathen.John@epa.gov>
Subject: RE: Ex. 5 - Deliberative Process

In case it's hard to read attachment on your iphone – not sure this is better but just in case it is – I've cut and pasted here.

FDA-EPA Fish Advice: Technical Information

This web page contains detailed information on the following topics:

1. Sortable table of fish species Ex. 5 - Deliberative Process concentrations.

2. How the chart for FDA's and EPA's fish advice was derived.

3. Recommended portion sizes for children based on age.

Sortable fish table

This table can be sorted

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Fish species
Anchovy
Atlantic croaker
Atlantic mackerel
Black sea bass
Bluefish
Buffalo fish
Butterfish
Carp
Catfish
Chilean sea bass/Patagonian toothfish
Clam
Cod
Crab
Crawfish
Flatfish (flounder, plaice, sole)
Grouper
Haddock
Hake
Halibut
Herring
King mackerel

Ex. 5 - Deliberative Process

Lobster, American
Lobster, spiny
Mahi mahi / dolphinfish
Marlin
Monkfish
Mullet
Orange roughy
Oyster
Pacific chub mackerel
Perch, freshwater
Perch, ocean
Pickerel
Pollock
Rockfish
Sablefish
Salmon, canned
Salmon, fresh/frozen
Sardine
Scallop
Scorpionfish
Shad
Shark
Sheepshead
Shrimp
Skate
Smelt
Snapper
Spanish mackerel
Squid
Striped bass (ocean)
Swordfish
Tilapia
Tilefish (from Gulf of Mexico)
Tilefish (from Atlantic Ocean)
Trout, freshwater
Tuna, albacore / white tuna, canned
Tuna, albacore / white tuna, fresh/frozen
Tuna, bigeye
Tuna, light , canned
Tuna, skipjack
Tuna, yellowfin
Weakfish/seatrout
White croaker/Pacific croaker

Ex. 5 - Deliberative Process

Whitefish	Ex. 5 - Deliberative Process
Whiting	

ND = no data

How FDA and EPA derived the categories in the fish chart

Ex. 5 - Deliberative Process

Equations for determining which category each fish went in

<image001.png>

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Factors used in the calculations

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Results

Ex. 5 - Deliberative Process

Recommended portion sizes for children based on age

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

From: Larimer, Lisa
Sent: Friday, September 25, 2015 3:29 PM
To: Hisel-Mccoy, Sara; Southerland, Elizabeth
Cc: Barash, Shari; Wathen, John
Subject: RE: Ex. 5 - Deliberative Process

I'm working on Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process But this is what you are looking for (attached). It explains Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

From: Hisel-Mccoy, Sara
Sent: Friday, September 25, 2015 3:24 PM
To: Southerland, Elizabeth
Cc: Larimer, Lisa; Barash, Shari; Wathen, John
Subject: RE: Ex. 5 - Deliberative Process

Lisa is on it and will send you something soon.

From: Southerland, Elizabeth
Sent: Friday, September 25, 2015 3:20 PM
To: Hisel-Mccoy, Sara
Cc: Larimer, Lisa; Barash, Shari; Wathen, John
Subject: Re: Ex. 5 - Deliberative Process

Can you get the calculations to me asap? Ex. 5 - Deliberative Process
Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Sent from my iPhone

On Sep 25, 2015, at 3:15 PM, Hisel-Mccoy, Sara <Hisel-McCoy.Sara@epa.gov> wrote:

Betsy,

Ugh. OK, so Sharon just returned from Asia and seems to be overwhelmed. See Lisa's note below. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Additionally, we could move Tom's meeting to earlier in the week, but I would only want to it if you could call in from WEFTEC and I have no idea if that is viable – or even worth it. Meanwhile Lisa is doing her

Ex. 5 - Deliberative Process

seems like a stretch but I'd like your take on that as well. Any other thoughts you have are most welcome.

Sara

From: Larimer, Lisa
Sent: Friday, September 25, 2015 1:58 PM
To: Hisel-Mccoy, Sara

Cc: Wathen, John; Barash, Shari
Subject: URGENT: Ex. 5 - Deliberative Process

I just got off the phone with Sharon Natanblut. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

I'm happy to talk to you about all this in depth when you get back from your meeting, but we have an issue of some urgency:

Ex. 5 - Deliberative Process

Another wrinkle: Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Lisa Larimer, P.E. | Team Leader

U.S. Environmental Protection Agency | Washington, DC

Office of Water | Standards and Health Protection Division

☎ (202) 566-1017 | ✉ larimer.lisa@epa.gov

Ex. 5 - Deliberative Process

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
Cc: Gude, Karen[Gude.Karen@epa.gov]; Corona, Elizabeth[Corona.Elizabeth@epa.gov]
From: Deener, Kathleen
Sent: Tue 6/7/2016 7:05:11 PM
Subject: Meeting with EWG on fish/mercury
EWG_MercuryinSeafood.pdf

Hi Betsy –

Tom Burke received a request from the Environmental Working Group to meet and discuss mercury and fish. Specifically, they said they want to share with us a report they recently issued (see attached) and discuss their thoughts on fish consumption advice.

We've scheduled this meeting for June 20 at 2:15 p.m. Would you or anyone else from your office like to attend? We will be in listening mode. I'm copying Karen Gude so Joel is aware. If you or others want to attend, please let me and Elizabeth Corona (copied here) know.

Thanks,

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

To: Jones, Enesta[Jones.Enesta@epa.gov]
Cc: Cassell, Peter[Peter.Cassell@fda.hhs.gov]
From: Eisenman, Theresa
Sent: Wed 1/18/2017 6:19:56 PM
Subject: RE: FDA Media Request - CBS radio for Fish Advice

Good point. Thanks!!

From: Jones, Enesta [mailto:Jones.Enesta@epa.gov]
Sent: Wednesday, January 18, 2017 1:16 PM
To: Eisenman, Theresa
Cc: Cassell, Peter
Subject: RE: FDA Media Request - CBS radio for Fish Advice

This looks fine to us. **Ex. 5 - Deliberative Process**

Ex. 5 - Deliberative Process

Thanks, Theresa!

From: Eisenman, Theresa [mailto:Theresa.Eisenman@fda.hhs.gov]
Sent: Wednesday, January 18, 2017 1:09 PM
To: Jones, Enesta <Jones.Enesta@epa.gov>
Cc: Cassell, Peter <Peter.Cassell@fda.hhs.gov>
Subject: RE: FDA Media Request - CBS radio for Fish Advice

Our SME was going to call that line at 1:30 p.m.

From: Jones, Enesta [mailto:Jones.Enesta@epa.gov]
Sent: Wednesday, January 18, 2017 1:08 PM
To: Eisenman, Theresa
Cc: Cassell, Peter
Subject: RE: FDA Media Request - CBS radio for Fish Advice

Theresa: What time is the intvu sked for?

From: Eisenman, Theresa [mailto:Theresa.Eisenman@fda.hhs.gov]
Sent: Wednesday, January 18, 2017 12:40 PM
To: Jones, Enesta <Jones.Enesta@epa.gov>
Cc: Cassell, Peter <Peter.Cassell@fda.hhs.gov>
Subject: FW: FDA Media Request - CBS radio for Fish Advice

Enesta, we have this interview lined up with the journalist. Let me know if you have concerns. We are boiling the sound bites to this:

Ex. 5 - Deliberative Process

From: Dooren, Jennifer
Sent: Wednesday, January 18, 2017 12:19 PM
To: Eisenman, Theresa; Natanblut, Sharon
Cc: Wagner, Rachel; Jones, Enesta
Subject: Re: FDA Media Request - CBS radio for Fish Advice

Yes Dr Mayne can do this - at 1;30 or later

Jennifer

From: Eisenman, Theresa

Sent: Wednesday, January 18, 2017 12:10 PM

To: Dooren, Jennifer; Natanblut, Sharon

Cc: Wagner, Rachel; Jones, Enesta

Subject: FDA Media Request - CBS radio for Fish Advice

Can Dr. Mayne or Dr. O do this radio interview?

Reporter: Mara Rubin

Organization: CBS radio network in NY

Ex. 6 - Personal Privacy

Subject: fish advice

Deadline: immediate

Additional information: They are requesting a brief interview (2-3 mins) to get soundbites for the hourly broadcast and to send to all affiliates. They are looking for the SME to provide an overview of the chart and explain the three categories on the chart.

Theresa Eisenman
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-2969 / Cell: 240-802-0934
theresa.eisenman@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

To: Cassell, Peter[Peter.Cassell@fda.hhs.gov]; Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Dooren, Jennifer[Jennifer.Dooren@fda.hhs.gov]; Wagner, Rachel[Rachel.Wagner@fda.hhs.gov]; Rebello, Heidi[Heidi.Rebello@fda.hhs.gov]; Rodriguez, Jennifer[Jennifer.Rodriguez@fda.hhs.gov]; Rubio, Teresa[Teresa.Rubio@fda.hhs.gov]; Quinn, Kathleen[Kathleen.Quinn@fda.hhs.gov]; Conover, Katie[Priscilla.Conover@fda.hhs.gov]; Mayne, Susan[Susan.Mayne@fda.hhs.gov]; Ostroff, Stephen[Stephen.Ostroff@fda.hhs.gov]; Jones, Enesta[Jones.Enesta@epa.gov]; Loop, Travis[Loop.Travis@epa.gov]; Dennis, Allison[Dennis.Allison@epa.gov]
From: Eisenman, Theresa
Sent: Wed 1/18/2017 5:48:17 PM
Subject: Media Monitoring - Fish Advice -- TIME: Here's Which Fish Pregnant Women Should Avoid

TIME: Here's Which Fish Pregnant Women Should Avoid: Gov

http://time.com/4637515/heres-which-fish-pregnant-women-should-avoid-gov/

•□□□□□□ Alexandra Sifferlin @acsifferlin

12:23 PM ET

Here's how to avoid fish that are high in mercury

For years, health professionals have advised pregnant women and parents of young children to eat fish but avoid types that are high in mercury. That advice remained confusing for some, since federal officials didn't clarify which fish are low in mercury and which ones are high.

On Wednesday, the U.S. Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) issued its final guidance on fish consumption, geared to pregnant and breast-feeding women, and parents of young children. The agencies continue to recommend that people eat two to three servings of lower-mercury fish per week.

This time around, the agencies also provided information on which fish are high in mercury and which are low. The mercury levels were calculated using data from the FDA and other sources. The new advice says women who are pregnant and breast-feeding and parents of young children should avoid seven fish that are high in mercury: tilefish from the Gulf of Mexico, shark, swordfish, orange roughy, bigeye tuna, marlin, and king mackerel.

Fish that are low in mercury include some of the most commonly consumed varieties like salmon, cod, shrimp and tilapia. You can see a chart of how fish rank here.

Grocers and retailers that sell fish are encouraged to post the advice as well as the fish reference chart to help people make informed and healthy decisions about what fish to purchase.

The FDA says that 50% of pregnant women in an agency survey reported eating fewer than the recommended amount of fish to eat. Fish are generally a good choice due to their high amounts of protein and healthy fat.

To: Jones, Enesta[Jones.Enesta@epa.gov]
From: Loop, Travis
Sent: Fri 1/13/2017 6:17:34 PM
Subject: Re: EPA/FDA Fish Advice

Are your edits in the attached? I will share with FDA if so

Travis Loop
Communications Director for Water
U.S. Environmental Protection Agency
Phone: 202.870.6922
Follow us on Twitter @EPAwater

On Jan 13, 2017, at 12:02 PM, Jones, Enesta <Jones.Enesta@epa.gov> wrote:

> Looks good! Still need to give it a good AP scrub.
>
> Quick comments:

Ex. 5 - Deliberative Process

Enesta Jones
U.S. EPA
Office of Media Relations
Office: 202.564.7873
Cell: 202.236.2426

"The root of all joy is gratefulness."

On Jan 13, 2017, at 11:30 AM, Loop, Travis <Loop.Travis@epa.gov> wrote:

Travis Loop
Communications Director for Water
U.S. Environmental Protection Agency
Phone: 202.870.6922
Follow us on Twitter @EPAwater

Begin forwarded message:

From: "Loop, Travis" <Loop.Travis@epa.gov>
Date: January 13, 2017 at 10:39:18 AM EST
To: "Wagner, Rachel" <Rachel.Wagner@fda.hhs.gov>
Cc: "Lee, Monica" <Lee.Monica@epa.gov>, "McSeveney, Megan" <Megan.McSeveney@fda.hhs.gov>, "Dooren, Jennifer" <Jennifer.Dooren@fda.hhs.gov>
Subject: RE: EPA/FDA Fish Advice

Rachel

Here are edits to the release. I think these are limited and just tried to address some clunky wording in one section and clarify a few minor words in other spots.

I will send the updated roll out in a little bit. We're just making edits to EPA's notifications.

Thanks.

Travis Loop

Director of Communications

Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

From: Wagner, Rachel [mailto:Rachel.Wagner@fda.hhs.gov]
Sent: Friday, January 13, 2017 9:52 AM
To: Loop, Travis <Loop.Travis@epa.gov>
Cc: Lee, Monica <Lee.Monica@epa.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Subject: RE: EPA/FDA Fish Advice

Hi Travis and Monica,

This reflects the updated time.

Thank you!

Kindly,

Rachel Askarinam Wagner, MS

U.S. Food and Drug Administration

Office of the Commissioner, Office of External Affairs

(t) 240.402.3621 | (m) 202.768.6431

rachel.wagner@fda.hhs.gov

From: Wagner, Rachel
Sent: Thursday, January 12, 2017 8:13 PM
To: Loop, Travis
Cc: Lee, Monica; McSeveney, Megan; Dooren, Jennifer
Subject: Re: EPA/FDA Fish Advice

Hi there,

So looks like we are going on Wednesday morning at 8:45. The Federal Register looks good.

Could we please get comments if possible tomorrow? We need to have things lined up.

Thank you so much!

Rachel Askarinam Wagner, MS
Office of External Affairs
US Food and Drug Administration
rachel.wagner@fda.hhs.gov

From: Loop, Travis

Sent: Thursday, January 12, 2017 12:09 PM

To: Wagner, Rachel

Cc: Lee, Monica; McSeveney, Megan; Dooren, Jennifer

Subject: Re: EPA/FDA Fish Advice

Thanks. We will review and get any comments to you ASAP.

Travis Loop

Communications Director for Water

U.S. Environmental Protection Agency

Phone: 202.870.6922

Follow us on Twitter @EPAwater

On Jan 12, 2017, at 12:03 PM, Wagner, Rachel <Rachel.Wagner@fda.hhs.gov> wrote:

> And, just an FYI, I just got word that this might move to the morning on Wednesday for a posting at 8:45. I will confirm when I know better from the Federal Register folks here at FDA, but the timing might be shifting so don't hold to the 4:15.
>
> Thank you so much!

Kindly,

Rachel Askarinam Wagner, MS

U.S. Food and Drug Administration

Office of the Commissioner, Office of External Affairs

(t) 240.402.3621 | (m) 202.768.6431

rachel.wagner@fda.hhs.gov

<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

From: Wagner, Rachel
Sent: Thursday, January 12, 2017 10:57 AM
To: 'Loop, Travis'; Lee, Monica
Cc: McSeveney, Megan; Dooren, Jennifer
Subject: EPA/FDA Fish Advice
Importance: High

Hi Travis and Monica,

I am happy to be able to now share our communication materials for fish advice for next week. We are not sure if it will be Wednesday or Thursday (Jan. 18 or 19) but we are targeting one of those days, and we anticipate a late in the day Federal Register notice and announcement. You will see that the tick-tock reflects a 4:15 posting and start of activities.

Please respond back with confirmation that you have received these and then let me know if you have edits ASAP. These documents have been vetted and

cleared through our subject matter experts and cleared through FDA's legal team (attorneys). There are 2 sets of QA because one is internal for responding to reporters, stakeholders, and others and one is for the website and a policy piece.

Thank you very much.

Kindly,

Rachel Askarinam Wagner, MS

Rollout Coordinator

U.S. Food and Drug Administration

Office of the Commissioner, Office of External Affairs

10903 New Hampshire Ave, Blg 32, Rm 5331

Silver Spring, MD 20993

(t) 240.402.3621 | (m) 202.768.6431

rachel.wagner@fda.hhs.gov

<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

<FDA Fish Advice Draft Release 01 12 17-LL+CL+BS.doc>

To: Natanblut, Sharon[Sharon.Natanblut@fda.hhs.gov]; Dooren, Jennifer[Jennifer.Dooren@fda.hhs.gov]; Wagner, Rachel[Rachel.Wagner@fda.hhs.gov]; Eisenman, Theresa[Theresa.Eisenman@fda.hhs.gov]; Cassell, Peter[Peter.Cassell@fda.hhs.gov]; Rebello, Heidi[Heidi.Rebello@fda.hhs.gov]; Rodriguez, Jennifer[Jennifer.Rodriguez@fda.hhs.gov]; Rubio, Teresa[Teresa.Rubio@fda.hhs.gov]; Quinn, Kathleen[Kathleen.Quinn@fda.hhs.gov]; Conover, Katie[Priscilla.Conover@fda.hhs.gov]; Mayne, Susan[Susan.Mayne@fda.hhs.gov]; Ostroff, Stephen[Stephen.Ostroff@fda.hhs.gov]; Jones, Enesta[Jones.Enesta@epa.gov]; Loop, Travis[Loop.Travis@epa.gov]; Dennis, Allison[Dennis.Allison@epa.gov]
From: Cassell, Peter
Sent: Wed 1/18/2017 4:04:27 PM
Subject: Clips on Fish Advice as of 11 am 1/18

FDA, EPA finalize advice recommending pregnant women eat more seafood (Politico)

By Catherine Boudreau

https://www.politicopro.com/agriculture/whiteboard/2017/01/fda-epa-finalize-advice-recommending-pregnant-women-eat-more-seafood-082360

Jan 18, 2017 10:48 AM EST

The FDA and EPA issued final advice on fish consumption today, recommending women who are pregnant or may become pregnant, and those who are breast feeding or have young children, eat at least eight ounces and up to 12 ounces per week of low-mercury seafood.

The updated guidance, originally proposed in June 2014, moves away from years of advice that focused on women in these circumstances limiting the amount of fish they eat.

“Fish are an important source of protein and other nutrients for young children and women who are or may become pregnant, or are breastfeeding," said Stephen Ostroff, FDA's deputy commissioner for foods and veterinary medicine. "This advice clearly shows the great diversity of fish in the U.S. market that they can consume safely."

The agencies said they took a "cautious and highly protective approach" in developing their guidance, advising the identified populations against certain kinds of seafood that may contain higher levels of mercury, such as tilefish from the Gulf of Mexico, shark, swordfish and bigeye tuna.

Fish lower in mercury include some of the most commonly eaten species in the United States, such as shrimp, pollock, salmon, canned light tuna, tilapia, catfish and cod, Ostroff added.

New regs for Thursday: Guitarfish, fish diet, airlines (TheHill.com)

BY TIM DEVANEY - 01/18/17 10:38 AM EST 1

http://thehill.com/regulation/314785-new-regs-for-thursday-guitarfish-fish-diet-airlines

Thursday's edition of the *Federal Register* contains new protections for guitarfish, recommendations for people who eat fish, and baggage fee requirements for airlines.

Here's what is happening:

Airlines: The Department of Transportation (DOT) is proposing new rulesfor airlines.

Airlines will be required to disclose the fees for checked bags and carry-on bags "wherever fare and schedule information is provided to consumers," the agency said Wednesday in a supplemental notice of proposed rulemaking.

This would require airline websites to disclose baggage fee information "at the first point in the search process where a fare is listed in connection with a specific flight itinerary, adjacent to the fare."

Ticket agents would also be required to disclose baggage fees.

The public has 60 days to comment.

Guitarfish: The National Marine Fisheries Service (NMFS) is moving forward with new protections for guitarfish.

The NMFS will list the blackchin guitarfish and common guitarfish as threatened species, the agency said Wednesday.

"We will not designate critical habitat for either of these species because the geographical areas occupied by these species are entirely outside U.S. jurisdiction," the agency said, "and we have not identified any unoccupied areas within U.S. jurisdiction that are currently essential to the conservation of either of these species."

The protections go into effect in 30 days.

Fish diet: The Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) are drafting new guidelines for eating fish.

The guidelines include advice for consumers who eat fish, including "questions and answers for those who want to understand the advice in greater detail."

Efficiency: The Department of Energy (DOE) is moving forward with new efficiency rules for ceiling fans.

The Energy Department's Office of Energy Efficiency and Renewable Energy announced Wednesday new ceiling fan energy conservation standards.

The changes go into effect in 60 days.

To: Hart, Daniel[Hart.Daniel@epa.gov]; Slotkin, Ron[slotkin.ron@epa.gov]
Cc: Orquina, Jessica[Orquina.Jessica@epa.gov]; Morin, Jeff[Morin.Jeff@epa.gov]; Jones, Enesta[Jones.Enesta@epa.gov]; Dennis, Allison[Dennis.Allison@epa.gov]
From: Loop, Travis
Sent: Wed 1/18/2017 3:01:14 PM
Subject: RE: graphic that snuck up

We are not placing this on our site – all we are doing is linking to FDA's webpage about the fish advice which includes the chart.

I think Ron makes some good points about how the graphic could be more useful and I will share that feedback with FDA and see if they will make updates.

Thanks, and sorry for the scramble and confusion on this one – the chart just came to us…

Travis Loop

Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

From: Hart, Daniel
Sent: Wednesday, January 18, 2017 9:09 AM
To: Slotkin, Ron <slotkin.ron@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
Cc: Orquina, Jessica <Orquina.Jessica@epa.gov>; Morin, Jeff <Morin.Jeff@epa.gov>; Jones, Enesta <Jones.Enesta@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>
Subject: RE: graphic that snuck up

+Allison in case Travis is oflline

Daniel (Danny) Hart | Director, Office of Web Communication, Office of Public Affairs, U.S. EPA | desk: 202-564-7577 | cell: 202-365-7095

From: Hart, Daniel
Sent: Wednesday, January 18, 2017 8:38 AM
To: Slotkin, Ron <slotkin.ron@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
Cc: Orquina, Jessica <Orquina.Jessica@epa.gov>; Morin, Jeff <Morin.Jeff@epa.gov>; Jones, Enesta <Jones.Enesta@epa.gov>
Subject: RE: graphic that snuck up

Travis, given that this is going in a release at 9:15 and that it appears there needs be updates to the graphic. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Daniel (Danny) Hart | Director, Office of Web Communication, Office of Public Affairs, U.S. EPA | desk: 202-564-7577 | cell: 202-365-7095

From: Slotkin, Ron
Sent: Tuesday, January 17, 2017 5:04 PM
To: Loop, Travis <Loop.Travis@epa.gov>
Cc: Hart, Daniel <Hart.Daniel@epa.gov>; Orquina, Jessica <Orquina.Jessica@epa.gov>
Subject: RE: graphic that snuck up

...OK… got it, a few questions…

Ex. 5 - Deliberative Process

Under the Best Choices…you list "Plaice", and on the same list you show Flounder and Sole. Is there a reason for listing Plaice when it is really sole? Is it sold under that name in the US? Better to put (Sole) after Plaice if you must show it ad leave Sole in the list.

Ex. 5 - Deliberative Process

We all must work together to anticipate, prepare and adapt to a changing climate

---

Ron Slotkin

Director, Office of Multimedia (OM)

U.S. Environmental Protection Agency

Office of Public Affairs (OPA)

William Jefferson Clinton Federal Building, Room 6330 A-B North
1200 Pennsylvania Ave. NW Mail code 1701A
Washington DC 20460

You can also reach me by:
202.564.6854 desk
202.904.6794 cell

FEDEX and UPS deliveries
use same address, change zip code > use 20004-2403 instead

For EPA staff: EPAtv s found at http://epatv.epa.gov (it only works with IE)
Also: looking for EPAtv on-demand or photos, multimedia or video guidance etc., go to http://intranet.epa.gov/media

From: Loop, Travis
Sent: Tuesday, January 17, 2017 2:46 PM
To: Slotkin, Ron <slotkin.ron@epa.gov>
Cc: Hart, Daniel <Hart.Daniel@epa.gov>; Orquina, Jessica <Orquina.Jessica@epa.gov>
Subject: graphic that snuck up

Ron

Tomorrow we issue a joint press release with FDA on our new advice for fish consumption to pregnant and nursing mothers. I Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Travis Loop

Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

To: Jones, Enesta[Jones.Enesta@epa.gov]
From: Loop, Travis
Sent: Wed 1/18/2017 2:51:08 PM
Subject: Fwd: live EPA pages for fish advice

Is this link in our release in the newsroom? Can you swap it out if not?

Travis Loop
Communications Director for Water
U.S. Environmental Protection Agency
Phone: 202.870.6922
Follow us on Twitter @EPAwater

Begin forwarded message:

From: "Lalley, Cara" <Lalley.Cara@epa.gov>
Date: January 18, 2017 at 9:43:17 AM EST
To: "Loop, Travis" <Loop.Travis@epa.gov>, "Dennis, Allison" <Dennis.Allison@epa.gov>
Cc: "Fuld, John" <Fuld.John@epa.gov>, "Younes, Lina" <Younes.Lina@epa.gov>
Subject: FW: live EPA pages for fish advice

We also have an alias that goes to our fish microsite homepage:
www.epa.gov/fishadvice

We have included a banner and prominent link in the upper right green box on that page for the new fish advice.

From: Lalley, Cara
Sent: Wednesday, January 18, 2017 9:35 AM
To: Loop, Travis <Loop.Travis@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>
Cc: Fuld, John <Fuld.John@epa.gov>
Subject: live EPA pages for fish advice

The first one is the most direct/comprehensive link for the advice, but we refer to the advice from lots of different fish pages:

https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish

https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish-documents

https://www.epa.gov/fish-tech/epa-fda-fish-advice-technical-information

https://www.epa.gov/choose-fish-and-shellfish-wisely/should-i-be-concerned-about-eating-fish-and-shellfish

https://www.epa.gov/fish-tech

https://www.epa.gov/choose-fish-and-shellfish-wisely/fish-and-shellfish-advisories-and-safe-eating-guidelines

https://www.epa.gov/choose-fish-and-shellfish-wisely

Cara Lalley

Communications Coordinator

Office of Science & Technology

U.S. EPA Office of Water

(202)566-0372 (p)

(202)566-1140 (f)

To: Cassell, Peter[Peter.Cassell@fda.hhs.gov]; Eisenman, Theresa[Theresa.Eisenman@fda.hhs.gov]; Dooren, Jennifer[Jennifer.Dooren@fda.hhs.gov]; Wagner, Rachel[Rachel.Wagner@fda.hhs.gov]; Rebello, Heidi[Heidi.Rebello@fda.hhs.gov]; Rodriguez, Jennifer[Jennifer.Rodriguez@fda.hhs.gov]; Rubio, Teresa[Teresa.Rubio@fda.hhs.gov]; Quinn, Kathleen[Kathleen.Quinn@fda.hhs.gov]; Conover, Katie[Priscilla.Conover@fda.hhs.gov]; Mayne, Susan[Susan.Mayne@fda.hhs.gov]; Ostroff, Stephen[Stephen.Ostroff@fda.hhs.gov]; Jones, Enesta[Jones.Enesta@epa.gov]; Loop, Travis[Loop.Travis@epa.gov]; Dennis, Allison[Dennis.Allison@epa.gov]
From: Natanblut, Sharon
Sent: Wed 1/18/2017 8:58:33 PM
Subject: RE: Media Monitoring - Fish Advice -- TIME: Here's Which Fish Pregnant Women Should Avoid

Here's NFI's quote from a Food Chem News story.

"We're concerned that the agencies have put out advice with myriad lists, categories, and an unclear narrative," NFI spokesman Gavin Gibbons says. "We are also concerned that the agencies have pushed out a document just 48 hours before the administration change that does not appear to follow much of FDA's own science on the issue."

From: Cassell, Peter
Sent: Wednesday, January 18, 2017 3:51 PM
To: Eisenman, Theresa; Natanblut, Sharon; Dooren, Jennifer; Wagner, Rachel; Rebello, Heidi; Rodriguez, Jennifer; Rubio, Teresa; Quinn, Kathleen; Conover, Katie; Mayne, Susan; Ostroff, Stephen; 'jones.enesta@epa.gov'; 'loop.travis@epa.gov'; 'dennis.allison@epa.gov'
Subject: RE: Media Monitoring - Fish Advice -- TIME: Here's Which Fish Pregnant Women Should Avoid

FDA Offers Guidance on Fish Intake for Kids, Pregnant Women

Agency recommends 2-3 servings of 'best choices' weekly

https://consumer.healthday.com/public-health-information-30/food-and-drug-administration-news-315/fda-offers-guidance-on-fish-intake-for-kids-pregnant-women-718807.html

WEDNESDAY, Jan. 18, 2017 (HealthDay News) -- A new U.S. government guideline classifies fish into three categories of safety to help pregnant women, breast-feeding mothers and parents of young children make healthy choices.

The 62 types of fish and shellfish included in the guideline are sorted into: best choices: eat two to three servings a week; good choices: eat one serving a week; and fish to avoid.

Nearly 90 percent of fish eaten in the United States fall into the best choices category, according to the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency.

Fifty percent of pregnant women eat fewer than 2 ounces of fish a week, which is far less than the recommended amount, the FDA said. Fish offers nutritional benefits important for growth and development during pregnancy and early childhood, the agency said.

The FDA and EPA recommend two to three servings of lower-mercury fish per week, or 8 to 12 ounces total. Twelve ounces is the recommended maximum weekly consumption, according to the new guidelines.

Those amounts are consistent with past recommendations, and consistent with the 2015-2020 Dietary Guidelines for Americans.

Lower-mercury fish and shellfish, part of the best choices group, include some of the most commonly eaten varieties, such as shrimp, pollock, salmon, canned light tuna, tilapia, catfish and cod.

The FDA and EPA recommend only one serving per week of fish from the good choices category, which includes bluefish, grouper, halibut, tilefish from the Atlantic Ocean, and albacore white tuna (canned, fresh or frozen).

A typical serving of fish for adults is 4 ounces before cooking. Serving sizes for children should be smaller and adjusted for their age and total calorie needs. Children should eat a variety of fish once or twice a week, according to the guideline.

"Fish are an important source of protein and other nutrients for young children and women who are or may become pregnant, or are breast-feeding. This advice clearly shows the great diversity of fish in the U.S. market that they can consume safely," said Dr. Stephen Ostroff, FDA Deputy Commissioner for Foods and Veterinary Medicine.

"This new, clear and concrete advice is an excellent tool for making safe and healthy choices when buying fish," he said in an FDA news release.

All fish contain at least some mercury, which can harm the brain and nervous system if consumed in high amounts over time. Children, pregnant or breast-feeding women, and women of childbearing age should avoid seven types of fish with higher mercury levels: tilefish from the Gulf of Mexico; shark; swordfish; orange roughy; bigeye tuna; marlin, and king mackerel.

People who fish recreationally and eat their catch should check for local advisories about mercury and other contaminants. If no local advisory is available, eat just one fish meal a week. Clean and trim fat and skin from locally caught fish, according to the guideline.

More information

The U.S. Food and Drug Administration has more from its guideline chart on advice on eating fish.

SOURCE: U.S. Food and Drug Administration, news release, Jan. 18, 2017

From: Eisenman, Theresa
Sent: Wednesday, January 18, 2017 12:48 PM
To: Cassell, Peter; Natanblut, Sharon; Dooren, Jennifer; Wagner, Rachel; Rebello, Heidi; Rodriguez, Jennifer; Rubio, Teresa; Quinn, Kathleen; Conover, Katie; Mayne, Susan; Ostroff, Stephen; 'jones.enesta@epa.gov'; 'loop.travis@epa.gov'; 'dennis.allison@epa.gov'
Subject: Media Monitoring - Fish Advice -- TIME: Here's Which Fish Pregnant Women Should Avoid

TIME: Here's Which Fish Pregnant Women Should Avoid: Gov

http://time.com/4637515/heres-which-fish-pregnant-women-should-avoid-gov/

•□□□□□□ Alexandra Sifferlin @acsifferlin

12:23 PM ET

Here's how to avoid fish that are high in mercury

For years, health professionals have advised pregnant women and parents of young children to eat fish but avoid types that are high in mercury. That advice remained confusing for some, since federal officials didn't clarify which fish are low in mercury and which ones are high.

On Wednesday, the U.S. Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) issued its final guidance on fish consumption, geared to pregnant and breast-feeding women, and parents of young children. The agencies continue to recommend that people eat two to three servings of lower-mercury fish per week.

This time around, the agencies also provided information on which fish are high in mercury and which are low. The mercury levels were calculated using data from the FDA and other sources. The new advice says women who are pregnant and breast-feeding and parents of young children should avoid seven fish that are high in mercury: tilefish from the Gulf of Mexico, shark, swordfish, orange roughy, bigeye tuna, marlin, and king mackerel.

Fish that are low in mercury include some of the most commonly consumed varieties like salmon, cod, shrimp and tilapia. You can see a chart of how fish rank here.

Grocers and retailers that sell fish are encouraged to post the advice as well as the fish reference chart to help people make informed and healthy decisions about what fish to purchase.

The FDA says that 50% of pregnant women in an agency survey reported eating fewer than the recommended amount of fish to eat. Fish are generally a good choice due to their high amounts of protein and healthy fat.

To: Jones, Enesta[Jones.Enesta@epa.gov]; Eisenman, Theresa[Theresa.Eisenman@fda.hhs.gov]
Cc: Cassell, Peter[Peter.Cassell@fda.hhs.gov]
From: Wagner, Rachel
Sent: Wed 1/18/2017 2:33:08 PM
Subject: RE: FDA and EPA issue final fish consumption advice

Thank you, Enesta. Really appreciate it!

Kindly,

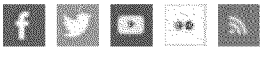
Rachel Askarinam Wagner, MS

U.S. Food and Drug Administration

Office of the Commissioner, Office of External Affairs

(t) 240.402.3621 | (m) 202.768.6431

rachel.wagner@fda.hhs.gov



From: Jones, Enesta [mailto:Jones.Enesta@epa.gov]
Sent: Wednesday, January 18, 2017 9:24 AM
To: Eisenman, Theresa
Cc: Cassell, Peter; Wagner, Rachel
Subject: Re: FDA and EPA issue final fish consumption advice

Thanks!

Enesta Jones

U.S. EPA

Office of Media Relations

Office: 202.564.7873

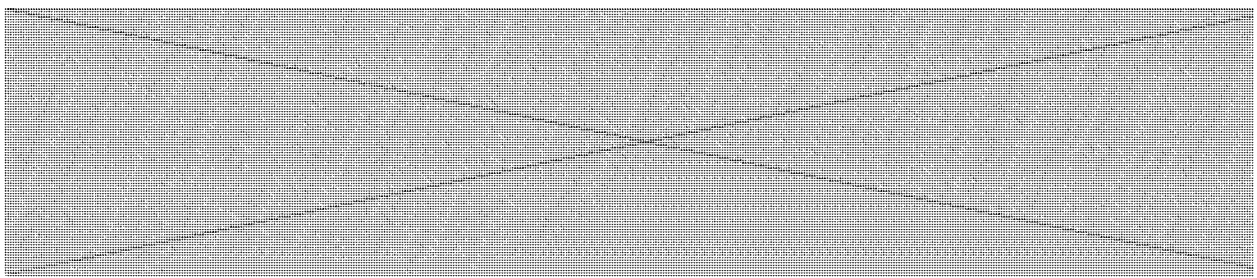
Cell: 202.236.2426

"The root of all joy is gratefulness."

On Jan 18, 2017, at 9:23 AM, Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov> wrote:

our release just went out …

From: FDA Office of Media Affairs [mailto:fdaoma@fda.hhs.gov]
Sent: Wednesday, January 18, 2017 9:19 AM
To: Eisenman, Theresa
Subject: FDA and EPA issue final fish consumption advice



FDA NEWS RELEASE

For Immediate Release: Jan. 18, 2017
Media Inquiries: FDA: Theresa Eisenman, theresa.eisenman@fda.hhs.gov, 301-796-2969;
EPA: Enesta Jones, 202.564.7873, jones.enesta@epa.gov
Consumer Inquiries: 888-INFO-FDA

FDA and EPA issue final fish consumption advice

Chart makes it easier than ever for pregnant women and others to choose from dozens of healthy and safe options; Nearly 90% of fish eaten in the U.S. fall into "best choices" category

Today, the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency issued final advice regarding fish consumption. This advice is geared toward helping women who are pregnant or may become pregnant – as well as breastfeeding mothers and parents of young children – make informed choices when it comes to fish that are healthy and safe to eat. (This advice refers to fish and shellfish collectively as "fish.")

To help these consumers more easily understand the types of fish to select, the agencies have created an easy-to-use reference chart that sorts 62 types of fish into three categories:

--"Best choices" (eat two to three servings a week)

--"Good choices" (eat one serving a week)

--"Fish to avoid"

Fish in the "best choices" category make up nearly 90 percent of fish eaten in the United States.

An FDA analysis of fish consumption data found that 50 percent of pregnant women surveyed ate fewer than 2 ounces a week, far less than the amount recommended. Because the nutritional benefits of eating fish are important for growth and development during pregnancy and early childhood, the agencies are advising and promoting a minimum level of fish consumption for these groups. The advice recommends 2-3 servings of lower-mercury fish per week, or 8 to 12 ounces. However, all fish contain at least traces of mercury, which can be harmful to the brain and nervous system if a person is exposed to too much of it over time. The maximum level of consumption recommended in the final advice is consistent with the previous recommended level of 12 ounces per week. The new advice is consistent with the 2015 - 2020 Dietary Guidelines for Americans.

For adults, a typical serving is 4 ounces of fish, measured before cooking. Serving sizes for children should be smaller and adjusted for their age and total calorie needs. It is recommended that children eat fish once or twice a week, selected from a variety of fish types.

"Fish are an important source of protein and other nutrients for young children and women who are or

may become pregnant, or are breastfeeding. This advice clearly shows the great diversity of fish in the U.S. market that they can consume safely," said FDA Deputy Commissioner for Foods and Veterinary Medicine Stephen Ostroff, M.D. "This new, clear and concrete advice is an excellent tool for making safe and healthy choices when buying fish." Choices lower in mercury include some of the most commonly eaten fish, such as shrimp, pollock, salmon, canned light tuna, tilapia, catfish and cod.

When updating the advice, the agencies took a cautious and highly protective approach to allow consumers to enjoy the benefits of fish while avoiding those with higher levels of mercury, which is especially important during pregnancy and early childhood. The average mercury content of each type of fish was calculated based on FDA data and information from other sources. The updated advice cautions parents of young children and certain women to avoid seven types of fish that typically have higher mercury levels: tilefish from the Gulf of Mexico; shark; swordfish; orange roughy; bigeye tuna; marlin; and king mackerel.

For fish caught recreationally, consumers are urged to check for local advisories where they are fishing and gauge their fish consumption based on any local and state advisories for those waters. If no information on fishing advisories is available, eat just one fish meal a week from local waters and also, avoid other fish that week. Consumers should clean and trim the fish they catch of fat and skin, since locally-caught fish may contain contaminants besides mercury that can be reduced by proper trimming and cooking, (e.g. broiling instead of frying can reduce some contaminants by letting fat drip away from the fish).

"It's all about eating and enjoying fish of the right kind and in the right amounts," said EPA Director for Water Science and Technology, Elizabeth Southerland, Ph.D. "This joint advice not only provides information for fish consumers who buy from local markets, but it also contains good information for people who catch their own fish or are provided fish caught by friends or relatives."

All retailers, grocers and others are urged to post this new advice, including the reference chart listing fish to choose, prominently in their stores so consumers can make informed decisions when and where they purchase fish. The agencies will be implementing a consumer education campaign working with a wide array of public and private partners featuring the new advice.

In June 2014, the agencies issued draft advice which encouraged pregnant women and others to eat between 8 and 12 ounces of fish a week of fish "lower in mercury" but did not provide a list showing consumers which fish are lower in mercury. The advice issued today also takes into account more than 220 comments received from academia, industry, nongovernmental organizations and consumers as well as an external peer review of the information and method used to categorize the fish.

For More Information:

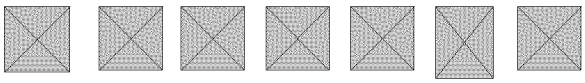
?□□ Eating Fish: What Pregnant Women and Parents Should Know

?□□ Advice About Eating Fish, From the Environmental Protection Agency and Food and Drug Administration; Revised Fish Advice; Availability

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

The EPA, a federal agency, works to protect all Americans from significant risks to human health and the environment where they live, learn and work. The agency focuses on all parts of society, from individuals to businesses and local governments. It develops regulations concerning natural resources, energy, transportation, agriculture, and industry and supports the various facets of environmental research and protection.

###



If you would like to stop receiving messages of this type in the future, you may unsubscribe

.

To: Jones, Enesta[Jones.Enesta@epa.gov]
From: Abrams, Dan
Sent: Wed 8/24/2016 1:21:55 AM
Subject: Re: OW FYI: Risk Policy Report RE: peer review seafood consumption advice

Yes sorry thought I said yes earlier! Thanks

Sent from my iPhone

On Aug 23, 2016, at 6:41 PM, Jones, Enesta <Jones.Enesta@epa.gov> wrote:

> All set?
>
> **Enesta Jones**
> **U.S. EPA**
> **Office of Media Relations**
> **Desk: 202.564.7873**
> **Cell: 202.236.2426**
>
> Begin forwarded message:
>
> **From:** "Jones, Enesta" <Jones.Enesta@epa.gov>
> **Date:** August 22, 2016 at 7:37:29 PM EDT
> **To:** "Abrams, Dan" <Abrams.Dan@epa.gov>
> **Cc:** "Valentine, Julia" <Valentine.Julia@epa.gov>, "Lee, Monica" <Lee.Monica@epa.gov>
> **Subject: Re: OW FYI: Risk Policy Report RE: peer review seafood consumption advice**
>
> Good evening!

Ex. 5 - Deliberative Process

FDA is the lead on this part, although we coordinate on press responses.

Here's some background on when we issued the updated draft advice in 2014:

Ex. 5 - Deliberative Process

Enesta Jones
U.S. EPA
Office of Media Relations
Desk: 202.564.7873
Cell: 202.236.2426

On Aug 22, 2016, at 11:41 AM, Abrams, Dan <Abrams.Dan@epa.gov> wrote:

Can you give me some background on this? We've gotten questions about this before from top tiers – I believe we did something with Time Mag on this. What is the advice, when is it out and what's our involvement compared to FDA?

From: Jones, Enesta
Sent: Thursday, August 18, 2016 5:27 PM
To: Abrams, Dan <Abrams.Dan@epa.gov>
Cc: Jones, Enesta <Jones.Enesta@epa.gov>; Valentine, Julia <Valentine.Julia@epa.gov>
Subject: OW FYI: Risk Policy Report RE: peer review seafood consumption advice

More of a FYI. FDA solicited our review of the responses since this is a FDA/EPA partnership. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Reporter: Maria Hegstad

What can you tell me about the material that is being/was peer reviewed? Is this another draft of the advice? Or another draft of the risk-benefit model that underlies the advice?

Ex. 5 - Deliberative Process

Why is the material undergoing peer review?

Ex. 5 - Deliberative Process

Is there a time frame for releasing the final advice?

Ex. 5 - Deliberative Process

Enesta Jones

U.S. EPA

Office of Media Relations

Desk: 202.564.7873

Cell: 202.236.2426

To: Eisenman, Theresa[Theresa.Eisenman@fda.hhs.gov]; Jones, Enesta[Jones.Enesta@epa.gov]
From: Cassell, Peter
Sent: Wed 1/18/2017 8:53:48 PM
Subject: RE: Media Monitoring - Fish Advice -- TIME: Here's Which Fish Pregnant Women Should Avoid

I have an alert set up and that didn't come through.

From: Eisenman, Theresa
Sent: Wednesday, January 18, 2017 3:53 PM
To: Jones, Enesta
Cc: Cassell, Peter
Subject: RE: Media Monitoring - Fish Advice -- TIME: Here's Which Fish Pregnant Women Should Avoid

Coping Pete … we are working on it, but have been shorted staffed today. I'll try to find that one.

From: Jones, Enesta [mailto:Jones.Enesta@epa.gov]
Sent: Wednesday, January 18, 2017 3:49 PM
To: Eisenman, Theresa
Subject: Re: Media Monitoring - Fish Advice -- TIME: Here's Which Fish Pregnant Women Should Avoid

Hi Theresa: Are you still tracking? I saw a good one from US News & World Report?

Enesta Jones

U.S. EPA

Office of Media Relations

Office: 202.564.7873

Cell: 202.236.2426

"The root of all joy is gratefulness."

On Jan 18, 2017, at 12:48 PM, Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov> wrote:

TIME: Here's Which Fish Pregnant Women Should Avoid: Gov

http://time.com/4637515/heres-which-fish-pregnant-women-should-avoid-gov/

•□□□□□□□ Alexandra Sifferlin @acsifferlin

12:23 PM ET

Here's how to avoid fish that are high in mercury

For years, health professionals have advised pregnant women and parents of young children to eat fish but avoid types that are high in mercury. That advice remained confusing for some, since federal officials didn't clarify which fish are low in mercury and which ones are high.

On Wednesday, the U.S. Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) issued its final guidance on fish consumption, geared to pregnant and breast-feeding women, and parents of young children. The agencies continue to recommend that people eat two to three servings of lower-mercury fish per week.

This time around, the agencies also provided information on which fish are high in mercury and which are low. The mercury levels were calculated using data from the FDA and other sources. The new advice says women who are pregnant and breast-feeding and parents of young children should avoid seven fish that are high in mercury: tilefish from the Gulf of Mexico, shark, swordfish, orange roughy, bigeye tuna, marlin, and king mackerel.

Fish that are low in mercury include some of the most commonly consumed varieties like salmon, cod, shrimp and tilapia. You can see a chart of how fish rank here.

Grocers and retailers that sell fish are encouraged to post the advice as well as the fish reference chart to help people make informed and healthy decisions about what fish to purchase.

The FDA says that 50% of pregnant women in an agency survey reported eating fewer than the recommended amount of fish to eat. Fish are generally a good choice due to their high amounts of protein and healthy fat.

To: Loop, Travis[Loop.Travis@epa.gov]
Cc: Dennis, Allison[Dennis.Allison@epa.gov]
From: Jones, Enesta
Sent: Tue 1/10/2017 6:43:00 PM
Subject: Re: Week of Jan 9th OW Rollouts

Thanks.

Enesta Jones
U.S. EPA
Office of Media Relations
Office: 202.564.7873
Cell: 202.236.2426

"The root of all joy is gratefulness."

On Jan 10, 2017, at 1:39 PM, Loop, Travis <Loop.Travis@epa.gov> wrote:

> correct
>
> Travis Loop
>
> Director of Communications
> Office of Water
>
> U.S. Environmental Protection Agency
>
> 202-870-6922
>
> loop.travis@epa.gov
>
> **From:** Jones, Enesta
> **Sent:** Tuesday, January 10, 2017 1:37 PM
> **To:** Loop, Travis <Loop.Travis@epa.gov>
> **Cc:** Dennis, Allison <Dennis.Allison@epa.gov>
> **Subject:** Re: Week of Jan 9th OW Rollouts

Just pr. No media call right?

Enesta Jones

U.S. EPA

Office of Media Relations

Office: 202.564.7873

Cell: 202.236.2426

"The root of all joy is gratefulness."

On Jan 10, 2017, at 1:36 PM, Loop, Travis <Loop.Travis@epa.gov> wrote:

> Now has reemerged with a 18th date as the target. Waiting for comms docs from FDA.
>
> Travis Loop
>
> Director of Communications
> Office of Water
>
> U.S. Environmental Protection Agency
>
> 202-870-6922
>
> loop.travis@epa.gov

From: Jones, Enesta
Sent: Tuesday, January 10, 2017 1:28 PM
To: Loop, Travis <Loop.Travis@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>
Subject: Re: Week of Jan 9th OW Rollouts

We're trying to plan our abbreviated and traffic jam week, next week.

Anything more on this? Could it still happen next Tuesday, Wednesday or Thursday?

Enesta Jones

U.S. EPA

Office of Media Relations

Office: 202.564.7873

Cell: 202.236.2426

"The root of all joy is gratefulness."

On Jan 6, 2017, at 8:53 AM, Loop, Travis <Loop.Travis@epa.gov> wrote:

> In limbo. FDA has the wheel and is talking to OMB and Joel to see if it will get out.

Travis Loop

Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

From: Jones, Enesta
Sent: Friday, January 06, 2017 8:52 AM
To: Dennis, Allison <Dennis.Allison@epa.gov>
Cc: Loop, Travis <Loop.Travis@epa.gov>
Subject: Re: Week of Jan 9th OW Rollouts

And oh, what about final fish advice? Still tent. for week of 1/16?

That's a tough week...2 Holidays + inaug jam...

Enesta Jones

U.S. EPA

Office of Media Relations

Office: 202.564.7873

Cell: 202.236.2426

"The root of all joy is gratefulness."

On Jan 6, 2017, at 8:44 AM, Dennis, Allison <Dennis.Allison@epa.gov> wrote:

Nothing

Sent from my iPhone

On Jan 6, 2017, at 8:42 AM, Jones, Enesta <Jones.Enesta@epa.gov> wrote:

So to be super clear: no press release ever? No statement? Nothing?

Enesta Jones

U.S. EPA

Office of Media Relations

Office: 202.564.7873

Cell: 202.236.2426

"The root of all joy is gratefulness."

On Jan 6, 2017, at 8:41 AM, Dennis, Allison <Dennis.Allison@epa.gov> wrote:

Correct! We killed it

Sent from my iPhone

On Jan 6, 2017, at 8:36 AM, Jones, Enesta

<Jones.Enesta@epa.gov> wrote:

Covering for Tricia today.

Ex. 5 - Deliberative Process

Enesta Jones

U.S. EPA

Office of Media Relations

Office: 202.564.7873

Cell: 202.236.2426

"The root of all joy is gratefulness."

On Jan 5, 2017, at 3:14 PM, Dennis, Allison <Dennis.Allison@epa.gov> wrote:

All,

Below is our tentative schedule for rollouts for next week:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

<BLOG drinking water PAG 1.11.17.docx>

<ROLL OUT PAGS FINAL 1.5.16.docx>

<Oregon Cadmium Final Rule_Rollout_FINAL.DOCX>

<ROLL OUT Lead Modeling 1.12.17.docx>

<PRESS RELEASE WIFIA NOFA 1.10.17.docx>

<ROLL OUT WIFIA NOFA 1.10.17.docx>

Cc: Dennis, Allison[Dennis.Allison@epa.gov]
To: Lalley, Cara[Lalley.Cara@epa.gov]
From: Jones, Enesta
Sent: Wed 1/18/2017 4:07:50 PM
Subject: Fwd: Clips on Fish Advice as of 11 am 1/18

I'll just forward...its easiest...

Enesta Jones
U.S. EPA
Office of Media Relations
Office: 202.564.7873
Cell: 202.236.2426

"The root of all joy is gratefulness."

Begin forwarded message:

From: "Cassell, Peter" <Peter.Cassell@fda.hhs.gov>
Date: January 18, 2017 at 11:04:27 AM EST
To: "Natanblut, Sharon" <Sharon.Natanblut@fda.hhs.gov>, "Dooren, Jennifer" <Jennifer.Dooren@fda.hhs.gov>, "Wagner, Rachel" <Rachel.Wagner@fda.hhs.gov>, "Eisenman, Theresa" <Theresa.Eisenman@fda.hhs.gov>, "Cassell, Peter" <Peter.Cassell@fda.hhs.gov>, "Rebello, Heidi" <Heidi.Rebello@fda.hhs.gov>, "Rodriguez, Jennifer" <Jennifer.Rodriguez@fda.hhs.gov>, "Rubio, Teresa" <Teresa.Rubio@fda.hhs.gov>, "Quinn, Kathleen" <Kathleen.Quinn@fda.hhs.gov>, "Conover, Katie" <Priscilla.Conover@fda.hhs.gov>, "Mayne, Susan" <Susan.Mayne@fda.hhs.gov>, "Ostroff, Stephen" <Stephen.Ostroff@fda.hhs.gov>, "'jones.enesta@epa.gov'" <jones.enesta@epa.gov>, "'loop.travis@epa.gov'" <loop.travis@epa.gov>, "'dennis.allison@epa.gov'" <dennis.allison@epa.gov>
Subject: Clips on Fish Advice as of 11 am 1/18

FDA, EPA finalize advice recommending pregnant women eat more seafood (Politico)

By Catherine Boudreau

https://www.politicopro.com/agriculture/whiteboard/2017/01/fda-epa-finalize-advice-recommending-pregnant-women-eat-more-seafood-082360

Jan 18, 2017 10:48 AM EST

The FDA and EPA issued final advice on fish consumption today, recommending women who are pregnant or may become pregnant, and those who are breast feeding or have young children, eat at least eight ounces and up to 12 ounces per week of low-mercury seafood.

The updated guidance, originally proposed in June 2014, moves away from years of advice that focused on women in these circumstances limiting the amount of fish they eat.

“Fish are an important source of protein and other nutrients for young children and women who are or may become pregnant, or are breastfeeding," said Stephen Ostroff, FDA's deputy commissioner for foods and veterinary medicine. "This advice clearly shows the great diversity of fish in the U.S. market that they can consume safely."

The agencies said they took a "cautious and highly protective approach" in developing their guidance, advising the identified populations against certain kinds of seafood that may contain higher levels of mercury, such as tilefish from the Gulf of Mexico, shark, swordfish and bigeye tuna.

Fish lower in mercury include some of the most commonly eaten species in the United States, such as shrimp, pollock, salmon, canned light tuna, tilapia, catfish and cod, Ostroff added.

New regs for Thursday: Guitarfish, fish diet, airlines (TheHill.com)

BY TIM DEVANEY - 01/18/17 10:38 AM EST 1

http://thehill.com/regulation/314785-new-regs-for-thursday-guitarfish-fish-diet-airlines

Thursday’s edition of the *Federal Register* contains new protections for guitarfish, recommendations for people who eat fish, and baggage fee requirements for airlines.

Here’s what is happening:

Airlines: The Department of Transportation (DOT) is proposing new rulesfor airlines.

Airlines will be required to disclose the fees for checked bags and carry-on bags "wherever fare and schedule information is provided to consumers," the agency said Wednesday in a supplemental notice of proposed rulemaking.

This would require airline websites to disclose baggage fee information "at the first point in the search process where a fare is listed in connection with a specific flight itinerary, adjacent to the fare."

Ticket agents would also be required to disclose baggage fees.

The public has 60 days to comment.

Guitarfish: The National Marine Fisheries Service (NMFS) is moving forward with new protections for guitarfish.

The NMFS will list the blackchin guitarfish and common guitarfish as threatened species, the agency said Wednesday.

"We will not designate critical habitat for either of these species because the geographical areas occupied by these species are entirely outside U.S. jurisdiction," the agency said, "and we have not identified any unoccupied areas within U.S. jurisdiction that are currently essential to the conservation of either of these species."

The protections go into effect in 30 days.

Fish diet: The Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) are drafting new guidelines for eating fish.

The guidelines include advice for consumers who eat fish, including "questions and answers for those who want to understand the advice in greater detail."

Efficiency: The Department of Energy (DOE) is moving forward with new efficiency rules for ceiling fans.

The Energy Department's Office of Energy Efficiency and Renewable Energy announced Wednesday new ceiling fan energy conservation standards.

The changes go into effect in 60 days.

To: Julia Valentine (valentine.julia@epa.gov)[valentine.julia@epa.gov]
From: Jones, Enesta
Sent: Wed 1/18/2017 9:47:16 PM
Subject: FW: Media Monitoring - Fish Advice -- TIME: Here's Which Fish Pregnant Women Should Avoid

She's all set.

From: Grantham, Nancy
Sent: Wednesday, January 18, 2017 3:53 PM
To: Jones, Enesta <Jones.Enesta@epa.gov>
Subject: RE: Media Monitoring - Fish Advice -- TIME: Here's Which Fish Pregnant Women Should Avoid

thanks

Nancy Grantham

Office of Public Affairs

US Environmental Protection Agency

202-564-6879 (desk)

202-253-7056 (mobile)

From: Jones, Enesta
Sent: Wednesday, January 18, 2017 3:52 PM
To: Grantham, Nancy <Grantham.Nancy@epa.gov>
Subject: FW: Media Monitoring - Fish Advice -- TIME: Here's Which Fish Pregnant Women Should Avoid

From: Cassell, Peter [mailto:Peter.Cassell@fda.hhs.gov]
Sent: Wednesday, January 18, 2017 3:51 PM

To: Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Wagner, Rachel <Rachel.Wagner@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rodriguez, Jennifer <Jennifer.Rodriguez@fda.hhs.gov>; Rubio, Teresa <Teresa.Rubio@fda.hhs.gov>; Quinn, Kathleen <Kathleen.Quinn@fda.hhs.gov>; Conover, Katie <Priscilla.Conover@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Ostroff, Stephen <Stephen.Ostroff@fda.hhs.gov>; Jones, Enesta <Jones.Enesta@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>
Subject: RE: Media Monitoring - Fish Advice -- TIME: Here's Which Fish Pregnant Women Should Avoid

FDA Offers Guidance on Fish Intake for Kids, Pregnant Women

Agency recommends 2-3 servings of 'best choices' weekly

https://consumer.healthday.com/public-health-information-30/food-and-drug-administration-news-315/fda-offers-guidance-on-fish-intake-for-kids-pregnant-women-718807.html

WEDNESDAY, Jan. 18, 2017 (HealthDay News) -- A new U.S. government guideline classifies fish into three categories of safety to help pregnant women, breast-feeding mothers and parents of young children make healthy choices.

The 62 types of fish and shellfish included in the guideline are sorted into: best choices: eat two to three servings a week; good choices: eat one serving a week; and fish to avoid.

Nearly 90 percent of fish eaten in the United States fall into the best choices category, according to the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency.

Fifty percent of pregnant women eat fewer than 2 ounces of fish a week, which is far less than the recommended amount, the FDA said. Fish offers nutritional benefits important for growth and development during pregnancy and early childhood, the agency said.

The FDA and EPA recommend two to three servings of lower-mercury fish per week, or 8 to 12 ounces total. Twelve ounces is the recommended maximum weekly consumption, according to the new guidelines.

Those amounts are consistent with past recommendations, and consistent with the 2015-2020 Dietary Guidelines for Americans.

Lower-mercury fish and shellfish, part of the best choices group, include some of the most commonly eaten varieties, such as shrimp, pollock, salmon, canned light tuna, tilapia, catfish and cod.

The FDA and EPA recommend only one serving per week of fish from the good choices category, which includes bluefish, grouper, halibut, tilefish from the Atlantic Ocean, and albacore white tuna (canned, fresh or frozen).

A typical serving of fish for adults is 4 ounces before cooking. Serving sizes for children should be smaller and adjusted for their age and total calorie needs. Children should eat a variety of fish once or twice a week, according to the guideline.

"Fish are an important source of protein and other nutrients for young children and women who are or may become pregnant, or are breast-feeding. This advice clearly shows the great diversity of fish in the U.S. market that they can consume safely," said Dr. Stephen Ostroff, FDA Deputy Commissioner for Foods and Veterinary Medicine.

"This new, clear and concrete advice is an excellent tool for making safe and healthy choices when buying fish," he said in an FDA news release.

All fish contain at least some mercury, which can harm the brain and nervous system if consumed in high amounts over time. Children, pregnant or breast-feeding women, and women of childbearing age should avoid seven types of fish with higher mercury levels: tilefish from the Gulf of Mexico; shark; swordfish; orange roughy; bigeye tuna; marlin, and king mackerel.

People who fish recreationally and eat their catch should check for local advisories about mercury and other contaminants. If no local advisory is available, eat just one fish meal a week. Clean and trim fat and skin from locally caught fish, according to the guideline.

More information

The U.S. Food and Drug Administration has more from its guideline chart on advice on eating fish.

SOURCE: U.S. Food and Drug Administration, news release, Jan. 18, 2017

From: Eisenman, Theresa
Sent: Wednesday, January 18, 2017 12:48 PM
To: Cassell, Peter; Natanblut, Sharon; Dooren, Jennifer; Wagner, Rachel; Rebello, Heidi; Rodriguez, Jennifer; Rubio, Teresa; Quinn, Kathleen; Conover, Katie; Mayne, Susan; Ostroff, Stephen; 'jones.enesta@epa.gov'; 'loop.travis@epa.gov'; 'dennis.allison@epa.gov'
Subject: Media Monitoring - Fish Advice -- TIME: Here's Which Fish Pregnant Women Should Avoid

TIME: Here's Which Fish Pregnant Women Should Avoid: Gov

http://time.com/4637515/heres-which-fish-pregnant-women-should-avoid-gov/

•□□□□□□□ Alexandra Sifferlin @acsifferlin

12:23 PM ET

Here's how to avoid fish that are high in mercury

For years, health professionals have advised pregnant women and parents of young children to eat fish but avoid types that are high in mercury. That advice remained confusing for some, since federal officials didn't clarify which fish are low in mercury and which ones are high.

On Wednesday, the U.S. Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) issued its final guidance on fish consumption, geared to pregnant and breast-feeding women, and parents of young children. The agencies continue to recommend that people eat two to three servings of lower-mercury fish per week.

This time around, the agencies also provided information on which fish are high in mercury and which are low. The mercury levels were calculated using data from the FDA and other sources. The new advice says women who are pregnant and breast-feeding and parents of young children should avoid seven fish that are high in mercury: tilefish from the Gulf of Mexico, shark, swordfish, orange roughy, bigeye tuna, marlin, and king mackerel.

Fish that are low in mercury include some of the most commonly consumed varieties like salmon, cod, shrimp and tilapia. You can see a chart of how fish rank here.

Grocers and retailers that sell fish are encouraged to post the advice as well as the fish reference chart to help people make informed and healthy decisions about what fish to purchase.

The FDA says that 50% of pregnant women in an agency survey reported eating fewer than the recommended amount of fish to eat. Fish are generally a good choice due to their high amounts of protein and healthy fat.